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Association between clinical trial activity and post-marketing access to new cancer medicines

Evidence from Finland and other Nordic countries

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Abstract

Clinical trials are essential for developing new medicines, generating evidence on safety and efficacy while also providing early access to therapies and strengthening clinical expertise. Despite this, clinical trial activity, including in oncology, has declined in Europe and the Nordic countries. At the same time, the number of approved cancer medicines has increased, yet access varies across countries and challenges persist even in high-income settings. However, empirical evidence on the relationship between clinical trial activity and post-marketing access to cancer medicines remains limited. This study aimed to describe trends in phase III oncology clinical trial activity, access to newly approved cancer medicines across the Nordic countries, and to explore the association between the clinical trial activity and the post-marketing access to new cancer medicines.

A 10-year retrospective observational study (2015–2024) was conducted using publicly available EU and Nordic data, complemented with commercial IQVIA first sales data. Clinical trial activity was measured both as the annual number of phase III oncology clinical trials and at the drug-level across countries. New cancer medicines were defined as those approved in EU from 2015 onwards. Post-marketing access milestones were measured using regulatory and administrative data to capture market entry, reimbursement/recommendation, and first sales depending on data availability in different countries. Time to access was defined as the delay between regulatory approval and each access dimension.

Clinical trial activity showed broadly similar trends across the Nordic countries. However, variation existed in both the volume and distribution of phase III trials for new cancer medicines, with the highest levels in Denmark and Sweden, the lowest in Iceland, and moderate levels in Finland and Norway. Access and time to access of new cancer medicines also varied between countries but differences were generally modest. At the drug level, medicines with more clinical trials were more likely to be available across countries, whereas no clear association was observed between total clinical trial activity and post-marketing access at the country level.

In conclusion, higher drug-level clinical trial activity was associated with greater post-marketing access to cancer medicines, although this finding should be interpreted with caution. Differences in access definitions and data availability highlight challenges in comparing access across countries and achieving real patient-level access. Overall, access is multidimensional and influenced by structural, regulatory, and economic factors beyond the possible role of clinical trial activity.

Key words: clinical trial activity, oncology, post-marketing access, patient access

Table of contents

Abbreviations

ATC	Anatomical Therapeutic Chemical
CA	Competent Authority
CHMP	Committee for Medicinal Products for Human Use
COHERE	Council for Choices in Healthcare
CTR	Clinical Trials Register
DKMA	Danish Medicines Agency
DMC	Danish Medicines Council
EEA	European Economic Area
EMA	European Medicines Agency
EU	European Union
EU CTR	EU Clinical Trials Regulation
FDA	Food and Drug Administration
Fimea	Finnish Medicines Agency
FinCCHTA	Finnish Coordinating Center for Health Technology Assessment
HTA	Health Technology Assessment
HUS	Helsinki University Hospital
IMA	Icelandic Medicines Agency
INN	International Non-proprietary Name
IQR	Interquartile Range
Kela	Social Insurance Institution of Finland
KOL	Key Opinion Leader
MA	Marketing Authorization
MEA	Managed Entry Agreements
NOMA	Norwegian Medicines Agency
NTC	New Therapies Council
OECD	Organization for Economic Co-operation and Development
PPB	Pharmaceuticals Pricing Board
RCT	Randomized Controlled Trial
SBU	Swedish Agency for Health Technology Assessment and Assessment of Social Services
SD	Standard Deviation
TLV	Dental and Pharmaceutical Benefits Agency
U.S.	United States
WHO	World Health Organization

1 Introduction

1.1 Current cancer burden

Cancer represents an increasing burden worldwide, mainly driven by demographic changes and improved cancer detection [1,2]. Nordic countries (Finland, Sweden, Norway, Denmark, and Iceland) perform exceptionally well in cancer care and are also counted among those with the highest cancer survival rates in Europe and globally [3,4]. However, cancer is still a major health concern with over 4 million new cancer cases and nearly 2 million cancer-related deaths reported in 2022 in Europe [5], and by 2035, cancer is expected to become a leading cause of death in Europe [6].

As cancer incidence continues to rise, oncology remains one of the most rapidly growing and expanding therapeutic areas in the pharmaceutical industry [7]. Recent decades have seen significant progress in cancer care resulting from advancements in prevention, early detection, drug therapies, and other treatment approaches [1]. The changes in approaches to cancer care are driven by advances in knowledge of cancer biology and pathophysiology. Genomic profiling of tumors enables a shift to more personalized medicine, and targeting specific molecular pathways minimizes toxicity related to conventional chemotherapeutic regimens [1]. Significant progress has also been achieved through the development of therapies that harness the body's immune system [8].

Access to innovative cancer treatments is critical for delivering high-quality care to patients [6]. Even though the number of approved cancer medicines as well as the number of approvals for new indications of existing medicines have increased over time, even affluent countries with publicly funded healthcare systems have faced challenges in access to cancer medicines in recent years [1,6]. Challenges identified in managing cancer medicines include for example rapidly rising launch prices, accelerated approval with incomplete data and variations in national willingness and capacity to fund treatments [1]. Additionally, the importance of clinical trials for access to cancer medicines as well as cross-country inequalities in clinical trial activity has been highlighted previously [6,9].

1.2 Study objective

The objective of this study was to examine whether national clinical trial activity is associated with post-marketing access to new cancer medicines in the Nordic countries, with particular focus on Finland. New cancer treatments can improve outcomes, but only if they are available in clinical setting [3]. Clinical trial activity contributes to evidence generation relevant to national decision-making processes and provides patients with early access to innovative therapies, which strengthens clinical expertise [6,10–12].

Thus, clinical trial activity may also have a potential role in post-marketing access to new cancer medicines.

Previous studies have documented differences in access to cancer medicines and clinical trial activity within oncology across countries [1,6,13–16]. Specifically, Finland has been reported to lag behind other Nordic countries in adopting pharmaceutical innovations, meanwhile the number of clinical trials generally has been declining for more than 25 years in Finland [10,17]. Additionally, in Finland, comparatively lower treatment outcomes have been observed for some cancers within the Nordics [18]. However, limited attention has been given to the relationship between clinical trial activity and post-marketing access of new cancer medicines. This study aimed to address this gap from a Nordic perspective.

1.3 Clinical trials: Focus on oncology

This section provides an overview of clinical trials in oncology, focusing on their role in drug development, decision-making, patient access, and broader societal impact. It also introduces the main factors guiding pharmaceutical companies' decisions on clinical trial site investments. In addition, it outlines current trends and challenges in clinical trial activity in Europe, Nordic countries, and Finland.

1.3.1 General purpose in drug development

Clinical trials are essential for developing new medicines. According to World Health Organization (WHO), clinical trials involve structured and systematic research in human participants to evaluate the safety, effectiveness and health outcomes of new therapeutical innovations [19]. Through several phases, clinical trials generate evidence on the drugs and determine the ones that can successfully be developed and approved to be used in clinical setting.

Clinical trials are divided into different phases (phase I-IV), each with a distinct objective, moving from early safety assessment to the evaluation of effectiveness and post-marketing surveillance. Phase I trials evaluate the safety and tolerability of a medicine in a small group of participants (typically 20-100), including healthy volunteers or patients with the disease, with the aim of determining a safe dosage range and identifying adverse effects. Phase II trials further assess the safety while also examine the sufficient efficacy of the treatment in a larger group of subjects with the condition, usually involving hundreds of patients. Phase III trials are conducted in even larger populations (typically 300-3000 patients) across multiple regions and countries with the primary objective of confirming the treatment's

efficacy in comparison with existing treatments. After regulatory approval, phase IV trials take place in further testing the efficacy and safety in several thousands of patients. [19–21]

Phase III clinical trials are considered “the gold standard” for evaluating the effectiveness of new medicines, and well-designed phase III studies continue to form the basis for regulatory approval [22–24]. Specifically, well-conducted phase III randomized controlled trials (RCTs) provide the most robust evidence supporting a medical intervention [25], and traditionally investigational drugs are expected to be supported by at least two pivotal RCTs [26]. The three main purposes of RCTs are to determine the efficacy of a new medicine compared to placebo (1), to compare the efficacy of a new medicine with that of standard therapy (2), and to assess whether a new medicine provides greater efficacy than standard therapy while associated with less morbidity (3) [22].

In oncology, uncertainty about the effects in clinical practice is particularly high as clinical data used for regulatory approval may solely rely on single-arm trials [27]. It has been demonstrated previously that out of 199 European Medicines Agency (EMA) approvals on cancer drugs targeting solid or hematological tumors, 80% were based on at least one RCT and 20% were not based on RCT at all prior to approval [28]. The primary objectives of clinical trials are to generate robust evidence to answer key clinical questions and to change clinical practice, and a single-arm phase III trial is reported not to be sufficient to meet these objectives [23]. Additionally, surrogate endpoints, such as tumor size or tumor marker blood tests, are commonly used measurements instead of overall survival or quality of life [27]. However, a cohort study evaluating drugs approved based on surrogate endpoints did not demonstrate improvement in overall survival or quality of life within five years after the approval [29].

Clinical trials not only generate clinical evidence but also have a crucial purpose in determining whether a medicine can successfully proceed through the development pathway. According to the Food and Drug Administration (FDA), the probability of an investigational drug to successfully complete phase III is approximately 25–30%, compared with 33% in phase II and 70% in phase I [21]. At the same time, phase III is generally the most expensive stage of clinical development and cancer drugs, in particular, exhibit higher failure rates during phase III trials compared with drugs in other therapeutic areas [30]. Failure to achieve proof of concept in phase II trial is one of the factors that may contribute to a higher probability of discontinuation in later-phase trials [31]. Consequently, greater investment in phase I and II trials has been proposed to generate the evidence necessary for effective phase III planning and to improve the likelihood of success [32].

1.3.2 Role in decision-making, patient access and societal impact

Evidence generated through clinical trials is central to later regulatory and funding decisions. In oncology, where treatments evolve rapidly, timely and robust clinical trial evidence is particularly crucial for informed healthcare decision-making. However, unmet needs in oncology and a need for faster access to therapies have led to an increasing trend for accelerated approval for new medicines and indications [1].

Expedited regulatory pathways, conditional approval by EMA and accelerated approval by FDA, allow drugs to receive MA on the basis of preliminary evidence that requires further verification after approval [33]. Special regulatory provisions may reduce time until marketing authorization (MA), but questions emerge on the benefits of these provisions to patients [33]. As comprehensive clinical evidence is often unavailable at the time of MA, it may also be delayed to become available in the post-approval phase, meaning that drugs whose benefit-risk profile is not fully established can remain on the market for years [34]. In Europe, the median duration to fulfill the specific post-approval obligations was found to be four years according to one study [34]. Additionally, FDA and EMA have even considered limited early evidence on the benefit-risk profiles of cancer drugs to be sufficient for regular approval [33].

The increasing use of expedited regulatory pathways has emphasized the importance of clinical trial evidence in informing regulatory and clinical decisions within oncology. Limited clinical evidence has been demonstrated to complicate decision-making on cancer drugs, as it may not support enough the benefit-risk and cost-effectiveness of new costly medicines [35]. It has been suggested more broadly that the regulatory process should produce more evidence that is meaningful for patients, clinicians, and healthcare payers [11]. Furthermore, it has been proposed that if regulators placed greater emphasis on the conduction of RCTs, more comparative data could be generated, ensuring timely evidence to support decision-making [11].

While clinical trials are essential for supporting regulatory approval and later decisions, they also provide patients with early access to innovative cancer therapies, sometimes several years before launch, with the potential to be more effective than standard care [6,17]. Early access does not only generate potential benefits for patients participating in the trial, but also increases the knowledge, skills, and clinical practice of the hospital staff [10]. However, it has been demonstrated that it takes several years for new medicines to become part of routine clinical practice [36]. Innovation-level factors, including effectiveness, safety, convenience, and therapeutic novelty have been considered as important aspects affecting the implementation outcomes [37]. Additionally, one study covering the oral targeted therapies for metastatic breast cancer suggested, that physicians' experience and familiarity with new medicines promote their use, whereas limited knowledge and confidence can delay adoption [38].

Lastly, clinical trials have a substantial impact on healthcare systems and broader societal and economic outcomes. Clinical trials provide direct financial benefits to healthcare systems by reducing treatment costs through sponsor-funded medications, as well as by generating revenue from running trials [10,17]. One report estimated that the average societal value of a single clinical trial to the healthcare system is approximately €10 million [10]. Furthermore, clinical trials are estimated to provide €1-1.5 billion in annual financial benefits to European Economic Area (EEA) health systems through sponsor payments and drug cost savings [16]. Clinical trials also support the growth and improvement of clinical infrastructure, attracting the further investment in healthcare [39].

1.3.3 Investment in clinical trials: Main drivers for country selection

Pharmaceutical companies consider a range of factors when selecting countries for clinical trials. While commercial potential has traditionally been viewed as a key driver, evidence suggests that clinical trial activity and commercial returns are not perfectly correlated. Increasingly, other considerations have been recognized as critical in shaping these decisions. In particular, country's clinical trial infrastructure and overall research environment play a pivotal role in making it an attractive location for trials. [39]

IQVIA has proposed an investment criteria framework identifying the key drivers of country selection for clinical trials. According to this framework, the three main drivers of country selection for clinical trials are clinical trial performance, access to expertise networks, and a supportive regulatory framework (Figure 1). In addition to these main drivers, disease epidemiology, including incidence and prevalence, diagnosis rates, and both past and ongoing clinical trial activity, contributes to a country's overall attractiveness. However, clinical trial costs appear to carry less weight in companies' investment decisions than other factors mentioned. [39]

Clinical trial performance, including speed and quality, is one of the three main decision drivers for site selection criteria for clinical trials, as timely action is key to optimizing both product value and market availability. Modern technologies can enable more effective recruitment while enhancing overall clinical trial performance, and countries that quickly establish advanced digital infrastructure are likely to secure a larger portion of clinical development activities in the future. However, differences in countries' digital maturity within healthcare systems lead to variations in their attractiveness. [39]

Besides trial performance, access to local expertise networks is critical for clinical trial success. Emerging biopharma and mid-sized pharmaceutical companies may even prioritize network access and knowledge over speed, especially when entering new therapeutic areas. On the other hand, large pharma

companies value key opinion leaders (KOLs) for their influence on downstream processes like market access and product launch. [39]

In addition to trial performance and expertise networks, regulators can speed up clinical trial innovation by launching initiatives, accepting novel designs, and using real-world evidence. These actions towards clinical trial optimization, including accelerated programs and approvals, as well as flexible and seamless multi-phase studies, are increasingly used, though companies remain cautious about implementation of these in decentralized regions. Additionally, access and reimbursement timelines may also be considered when evaluating the country's regulatory framework. [39]

It is proposed previously, that healthcare policymakers must understand the challenges pharmaceutical companies face in running clinical trials so their system can stand out and attract more trials [39]. The main drivers presented in this chapter may help to explain the trends and problems seen in clinical trial industry today.

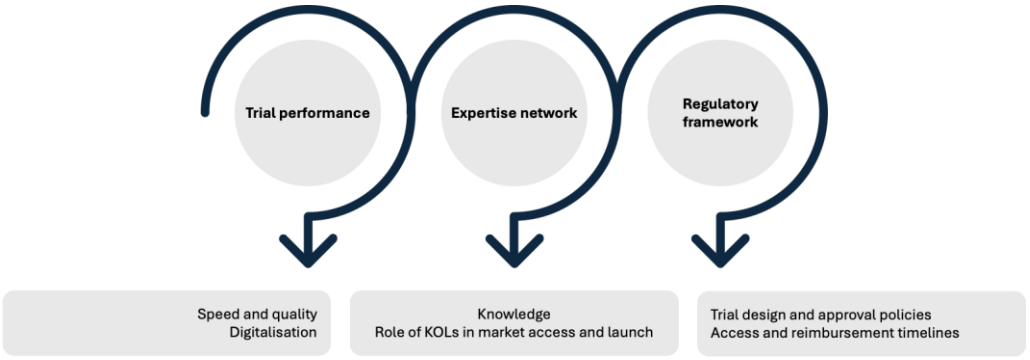

Figure 1. Key factors driving company decisions on clinical trial site investments. (KOL = Key Opinion Leader)

1.3.4 Current trends and challenges in Europe, Nordics, and Finland

Currently, most of the clinical research is taking place outside Europe. In 2023, 7990 commercial clinical trials were initiated globally, of which approximately 997 trials were conducted within the EEA [40]. Additionally, while the amount of clinical trials has increased 38% globally during the past decade, the EEA's share of global clinical trials has declined by half during that time [16]. This declining trend is mainly driven by a decrease in phase I trials [16].

Globally, the growth in commercial trials has been largely driven by an increase in phase I trials, whereas the EEA has experienced decline in phase I trials. In contrast to the global picture, trials conducted in the EEA are more common in phase II and III. Even though late-stage trials are particularly important for patient access to new treatments, a decline in early-phase trials may limit future trial opportunities.

This loss of share has been suggested to be linked with several factors, such as more favorable regulatory and funding environment in competing areas (e.g. Asia and the U.S.) and increasing clinical trial capabilities in non-EEA countries, including faster trial start-up timelines and recruitment. However, recruitment performance varies significantly across countries, with Poland, Spain and Denmark demonstrating relatively fast recruitment timelines within EEA. [16]

Another contrast to global picture is that more than one third of trials in EEA are multi-country whereas globally majority of trials are single-country, with the U.S., China, India, and Japan driving the rise in single-country trials. To be mentioned, from Nordic countries, Sweden, Denmark, and Norway are among the Top 10 EEA countries holding the highest number of single-country commercial trials. Overall, the EEA's share of global commercial trials reduced from 22% in 2013 to 12% in 2023. However, when considering only multi-country commercial trials, EEA maintained stronger position: the global share declined from 25% to 19% during the same period. This trend likely reflects both the expanding clinical trial infrastructure across the EEA and the need for multinational recruitment to achieve adequate patient sample sizes. [16]

In the EEA, oncology continues to be the dominant therapeutic area, representing over 25% of new trial initiations in 2023 [16]. In oncology specifically, EEA has experienced a contrasting trend compared to the U.S., where commercial clinical trial starts increased by 25% during 2018-2023, while decreased by 22% in the EEA [16]. Additionally, across European Union (EU) countries, inequalities to access to oncology clinical trials are recently documented, one study demonstrating that the availability of clinical trials has been found to range from less than 2 trials to more than 10 trials per 100,000 inhabitants [6]. The study showed that Denmark had clearly higher oncology clinical trial activity than other Nordic countries in 2009–2019. Norway ranked second, Sweden and Finland had relatively similar levels, and Iceland's activity was clearly lower. Overall, within EEA, there has been a shift in clinical trial activity towards Southern Europe, driven by the performance of Spain, whereas a consistent decline since 2018 has been seen in Northern Europe (Sweden, Norway, Finland) [16].

When considering Finland, the number of clinical trials has been declining for more than 25 years [10]. Specifically, in recent years, there has been a decline in the number of commercial clinical trials conducted in Finland. This downward trend partly reflects a Europe-wide phenomenon described earlier, while national factors have also contributed to the decline in Finland's competitiveness. Finland's commercial clinical trial infrastructure is fragmented and managed at the local level, causing challenges in both the initiation and organization of trials as well as in their practical implementation. Pharmaceutical companies might see the system complicated, which ultimately can weaken Finland's position as an attractive location for clinical research and result in the exclusion from new clinical trials in a competitive global landscape. [40]

Finland's fragmented infrastructure, and local-level organizational challenges reflect broader issues faced in oncology clinical trials, highlighting pressures on trial design, site selection, and patient recruitment. Clinical trials are becoming more complex due to targeted therapies and limited eligible patient populations. The increasing complexity of novel innovations has even led pharmaceutical companies to systematically reduce the number of trial sites. A mounting pressure on investigator sites and patient availability create competition in oncology, which is a highly innovative therapeutic area. This trend places pressure on included trial sites while also leading to a loss of potential benefits for countries excluded from conducting trials. [39]

In addition to these challenges, recent regulatory changes in Europe have also impacted the clinical trial activity. The primary challenge at European level is considered to be the EU Clinical Trials Regulation (EU CTR), implemented on 31 January 2022 [41], which changed the clinical trial approval process [40]. Even though EU CTR aims to harmonize the processes in Europe in the long-term [41], it has reported to introduce delays associated with the approval process [40]. To understand the trends and challenges in oncology clinical trial activity is important because clinical trials represent a key stage in the development pathway of medicines and partly shape access to new cancer medicines.

1.4 Access to cancer medicines: Definitions

This section presents the complex pathway of cancer medicines. A cancer medicine must undergo multiple stages before becoming available to patients. Following clinical trials, these stages include regulatory approval, pricing and reimbursement, and uptake and utilization [6]. Thus, patient access to new cancer medicines is multidimensional, and according the Organization for Economic Co-operation and Development (OECD) report in 2020 [1], the pathway from regulatory approval to uptake and utilization can be described with three main definitions: availability, affordability and accessibility. These definitions and the factors influencing them are illustrated in Figure 2 and described in more detail in the following chapters 2.2.1-2.2.3.

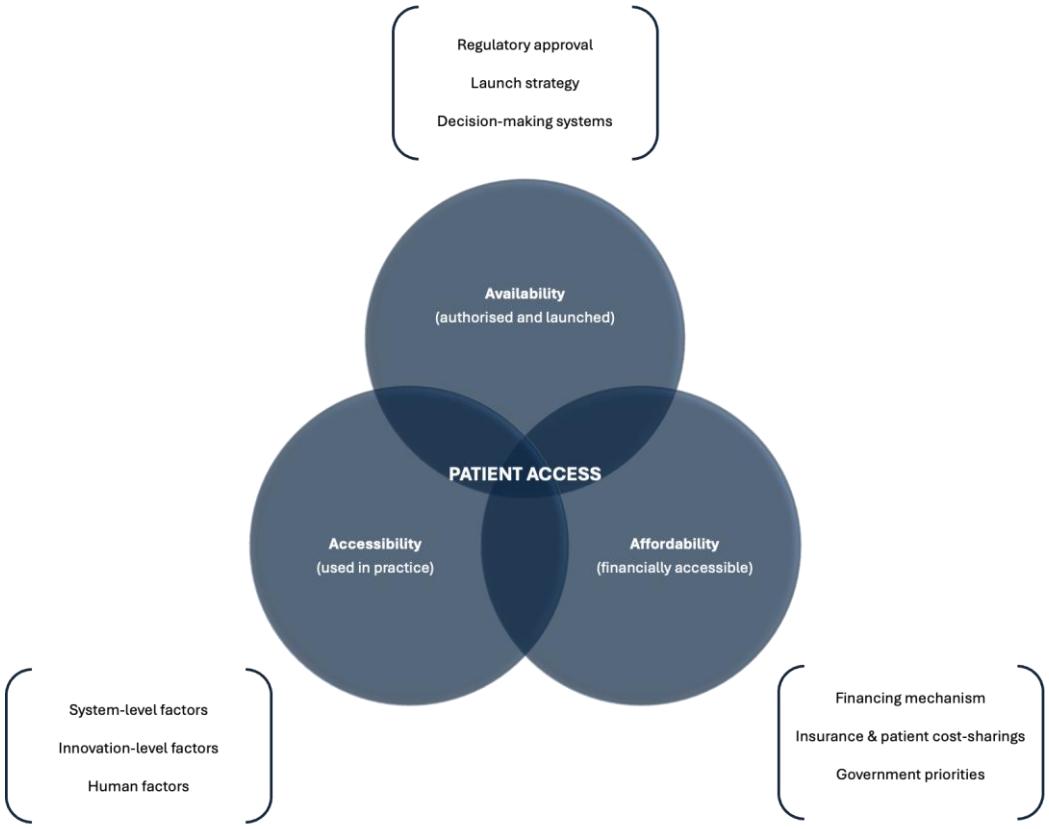

Figure 2. Patient access to medicines and factors influencing it.

1.4.1 Availability

Availability in the market is the first step, when determining patient access to medicines. Availability covers the regulatory approval and launch of the medicine by manufacturer company [1]. Regulatory body assesses the safety, quality, and effectiveness of new medicines, and in all EU countries, as well as in EEA countries Norway, Iceland and Liechtenstein, the EMA is responsible for that [42]. According to EMA's guidelines, all new cancer medicines must be scientifically evaluated through centralized procedure to receive MA [42]. The centralized MA allows the MA holder to distribute the medicine and enable access to the medicine for patients and healthcare professionals in all EU and EEA countries throughout the single application [42]. However, once the centralized MA is approved, it does not directly mean the medicine is on the market in those countries, as under EU law, EMA cannot authorize the actual marketing of the medicine in the specific EU countries [42].

It has been demonstrated previously, that within oncology, pharmaceutical companies typically apply for regulatory approval first by FDA meaning that medicines are first marketed in the U.S. According to one study, which examined trends in regulatory review times for new cancer medicines between FDA, EMA, Swissmedic, Pharmaceutical and Medical Devices Agency (in Japan), Health Canada, and Therapeutic Goods Administration (in Australia), FDA was the regulator to approve a new medicine

first of 80% of drug approval cases [43]. Further, among drugs first approved by the FDA, the median delay to receive approval from the EMA was 9.7 months [43]. However, initiatives are under discussion to accelerate cancer medicine approvals in the EU in the context of a major reform of EU Pharmaceutical Legislation, which aim to increase access to medicines, streamline procedures, and boost innovation [44].

Regulatory approval is later followed by launch. Product launch is tightly linked to medicine availability and typically occurs as soon as possible after granting MA [1]. The availability of a medicine in a country depends not only on whether it has received regulatory approval but also on how quickly it is launched on the market [1]. Thus, delays between approval and launch can limit patient access, even when a medicine is formally authorized. According the OECD report in 2020, the elapsed time between regulatory approval and launch is affected by two factors including the launch strategy of the company and the operational characteristics of regulatory and coverage decision-making systems [1]. Additionally, market size and national pharmaceutical policies play a role in a company's launch strategy [45].

A previous study has found that the U.S. remain the primary launch country for new medicines, and that there is an average delay of around one year from launch in the U.S. to launch in other major OECD countries (Australia, Canada, France, Germany, Italy, Japan, and the United Kingdom) [14]. However, same study demonstrated that the new drugs most valuable to industry tend to be launched widely across multiple countries [14]. The study suggested that greater pricing freedom, whether economic reviews take place alongside or after regulatory approval, and supply chain factors could justify differences in launch timing. Additionally, to further support those observations, another study has shown that in many countries, only a minority of new drugs are ultimately launched, and even when they are, patients often experience delays of several years compared with other markets [46]. The study proposed that factors such as pricing policies and intellectual property protections contribute to these variations. Even though these studies are not cancer specific, they demonstrate well how the timing of drug launch and thus the availability of new drugs in individual countries can vary due to different factors.

1.4.2 Affordability

Medicine availability is followed by affordability, which covers both individual and societal level affordability [1]. In its simplicity, affordability refers to whether the medicine is financially accessible [1]. The rising costs of cancer medicines is a significant phenomenon nowadays, and discussions of cancer drugs is increasingly referred to the term "financial toxicity". One study showed that the cumulative annual drug costs for certain cancer therapies (ipilimumab, sipuleucel-T, bevacizumab, paclitaxel, lenalidomide, bortezomib, imatinib mesylate, alemtuzumab, ofatumumab, brentuximab vedotin, and dasatinib) range from $60,000 to $120,000 per patient [47]. However, studies have indicated lower launch

prices in European countries than in the U.S., which might be explained by government price regulation, Health Technology Assessment (HTA) system, and direct price negotiations between HTA agencies and manufacturers in Europe [48].

Due to the high cost of cancer medicines, a vast majority of them need funding from third-party payers to maintain individual affordability. Third-party payers include for example government and private health insurance schemes that cover the costs of cancer treatment in most OECD countries [1]. Despite a coverage, patients may still be liable to pay user charges or cost-sharing requirements, which can limit access by causing financial burden on patients or their families [1]. Cost-sharing requirements include for example co-insurance, where insured person pays a certain percentage (e.g. 10%) of the cost of the medical service, and fixed co-payment, which is paid by insured individual for the consumption of a healthcare service (e.g. per hospital day) [1]. In contrast to medicines with coverage, hospital-administered medicines are generally financed directly by the healthcare system and are not subject to reimbursement schemes, meaning that patients typically do not pay for these medicines out-of-pocket. Finally, individual affordability is determined by factors including coverage of the medicine, patient's insurance status, the level of patient cost-sharing, and the type of financing mechanism applied.

Besides individual affordability, societal affordability is also an important consideration, referring to the affordability of medicines from the healthcare system's perspective. It encompasses several dimensions but primarily focuses on how treatments can be financed in a sustainable manner. Societal affordability is influenced by government priority setting and resource allocation reflecting how healthcare is valued relative to other public spending and the allocated resources dedicated to new medicines. Moreover, government priorities and resource allocation are shaped by broader societal values. [1]

Unlike EMA's centralized MA decisions, decisions on reimbursement are made at national level [35,49]. The criteria for reimbursement vary across European countries, but reimbursement decision is most commonly based on the relative effectiveness often referred to efficacy/effectiveness assessment conducted by HTA agencies [50]. Additionally, budget-impact, cost-effectiveness, and other factor such as ethical and social, play a role in reimbursement decisions [50]. Even though relative effectiveness is the most frequently used criterion to support reimbursement decisions of new cancer drugs, the budget impact of new cancer medicines is becoming more important factor to support reimbursement decisions [6]. Rising prices of cancer medicines and rising cancer expenditure are likely to contribute to this phenomenon [6].

Evidence-based care requires reliable data on a medicine's real-world performance, which is often incomplete at the time of pricing and reimbursement assessment of cancer medicines [6]. As mentioned previously, it is common in oncology, that regulatory approval of medicines is not always supported by

large, phase III RCTs; instead, it often relies on evidence from phase II or single-arm studies and, in some cases, on surrogate endpoints to assess treatment effects [27]. Supporting this observation, it has been indicated previously, that regulatory body in charge of granting MA may accept some degree of clinical uncertainty, which causes a gap in requested clinical evidence by HTA versus available clinical evidence, further affecting the efficacy/effectiveness assessment and decisions on medicine coverage [49].

1.4.3 Accessibility

The final step in the pathway towards patient access to cancer medicines is accessibility. It refers to the ability of patients to actually obtain the medicine and fill a prescription for the medicine in practice [1]. Decisions affecting accessibility are considered at national, regional or even individual hospital level [35]. New medicines are often introduced first in university hospitals and comprehensive cancer centers, and wider adoption may delay until clinical guidelines are revised and healthcare professionals are adequately trained [6]. Thus, decisions regarding uptake of medicines play a certain role in the patient access to treatments.

The reimbursement decision of medicine alone does not automatically guarantee patient access to it. Even countries with high reimbursement rates have been characterized by low utilization in clinical practice [6]. Furthermore, this issue is also relevant for hospital-administered medicines, which are not subject to reimbursement schemes. For example in Finland, access to cancer medicines is complex and after national recommendations on new cancer medicines, uptake is still decided at the individual hospital level causing possible differences in access to medicines across regions [51]. Disparities in uptake of new medicines have been demonstrated and partly explained by economic factors, particularly investment in health care and cancer care, while most variation is caused by non-economic differences [52]. One study grouped factors affecting the implementation of health innovations into structural, organizational, innovation, patient, and provider level factors [53], demonstrating its multi-dimensional approach.

The factors affecting the implementation represent different influences on how successfully a health innovation is implemented in practice [53]. Structural factors relate to the broader external environment, such as policies, economic conditions, and infrastructure. Organizational factors include internal characteristics such as leadership, culture, and how organization values evidence-based innovation. Innovation-level factors cover the characteristics of the intervention itself, including its perceived benefits compared to existing therapies. Patient-level factors involve patient beliefs, motivation, and behaviors, which can influence both adoption and outcomes of the innovation. Lastly, provider-level factors refer to healthcare professionals' attitudes, skills, and willingness to implement the innovation.

As discussed in the chapter 2.1.2, physicians' prior experience of new cancer medicines may facilitate their uptake [38].

Nordic countries share many similarities in their healthcare systems, but they have been found to differ in how new cancer medicines are distributed, adopted through Managed Entry Agreements (MEAs), and made available to patients [2]. MEAs are contracts between pharmaceutical companies and healthcare payers that primarily allow coverage of new medicines while manage financial or clinical uncertainty [54]. Because clinical uncertainties are common in oncology, use of MEAs has risen in recent decades within oncology [54]. Previous study demonstrated that MEAs can facilitate the reimbursement for medicines that would otherwise not be funded due to uncertainty, while they may also delay final reimbursement decisions [55]. As reimbursement is followed by uptake and utilization, MEAs may possibly indirectly affect later adoption of new cancer medicines.

1.5 Access to cancer medicines in the Nordic countries

This section describes access to cancer medicines in the Nordic countries, with a focus on the role of HTA in decision-making. It provides an overview of HTA systems in the Nordic context and outlines country-specific processes for the assessment, reimbursement, and implementation of new cancer medicines. Nordic healthcare systems are publicly financed and aim to ensure equitable access to care with low cost-sharing [56]. While these systems share common structural features [56], differences in policy implementation across countries may influence decision-making and access pathways. In this context, HTA plays a central role in evaluating the value of new cancer medicines.

1.5.1 Health Technology Assessment: Overview and Nordic context

HTA is a commonly applied evaluation framework designed to support decision-making. WHO describes HTA as a multidisciplinary and transparent process that evaluates the value of health technologies to support evidence-based decision-making and policy guidance in healthcare systems. It has a crucial role in translating medical innovations into real-world setting, as it functions as a bridge between research evidence and policy-making. [57]

While EMA, in terms of granting MA, primarily evaluates medicinal products based on their safety and efficacy, HTA's evaluation process is much wider as it addresses direct and intended effects, as well as indirect and unintended consequences of new medicines [57]. HTA considers, in addition to safety and efficacy, patient-reported and real-world outcomes, economic value, and broader social, ethical, legal, and policy implications [58]. National pricing and reimbursement decisions are a crucial part of HTA,

while they also defines access to newly approved medicines [59]. Thus, HTA has increasingly become a critical stage in making efficacious and economically viable medicines available to patients. However, according to one study, the average time of HTA process for five cancer medicines in six countries (Spain, Italy, France, Germany, England, Canada) was 15 months, compared to the 6 month target set by European Commission [60].

HTA is a widely used tool, and at some extent, it is used throughout Europe. However, its role in decision-making, price negotiations, and funding determinations varies considerably between countries. In some countries, HTA recommendations directly determine coverage decisions (so-called binding recommendation), whereas in others, HTA serves only as an advisory assessment for healthcare systems when deciding whether to include a technology on the reimbursement list or not (non-binding recommendation). According to one study covering 51 countries mainly in Europe, the majority of recommendations (81%) seemed to be non-binding with uncertain impact on reimbursement negotiations. [61]

Further, decision-making criteria involved in the assessment vary across countries, and especially the inclusion of cost-effectiveness evaluations and price negotiations have found to notably influence the decisions on medicines. According to a previous study, the inclusion of cost-effectiveness assessments significantly increased the proportion of negative recommendations, while price negotiations significantly reduced the proportion of negative recommendations. However, differences in HTA outcomes can still occur even when countries use the same criteria or procedures, due to differences in how evidence is assessed and interpreted. [62]

In the Nordic countries, the implementation of HTA is shaped not only by the assessment procedures themselves but also by structural and policy features of the healthcare systems. Fundamentally, a Nordic healthcare system covers three main levels including the goals and aspirations of society (1), the institutional and structural design (2), and the policy application within the structural dimensions (3). The three levels differ primarily in terms of their stability: changes at the first level occur very slowly and are rare, while changes at the second and, especially, at the third level tends to occur more frequently. Despite the similarities, differences exist between the Nordic countries mostly at the third level covering the policy design. [56]

One important feature influencing access to medicines in Nordic is the decentralized structure, meaning that decision-making responsibility for healthcare delivery is delegated to regional, county, or municipal level [56]. The organisation of HTA systems is shaped by the structure of the healthcare system [61], and while decentralization provides certain benefits, it may complicate decision-making for new medicines [63]. Decentralized structure can complicate medicine launches, as the process becomes fragmented [63], and

may lead to differences in the timing and availability of new drugs. However, considerable variation occurs between Nordic countries in the degree of decentralization and in how the levels coordinate with each other [56]. Further, one study demonstrated notably differences in time from MA to reimbursement of outpatient cancer medicines between the Nordic countries, from an average of 416 days in Sweden to 895 days in Denmark [2].

In addition to healthcare structure, financing and distribution mechanisms further shape HTA processes and access pathways for new medicines in Nordic. According to previous study on uptake of cancer medicines in Nordic countries, in Finland, Sweden, Norway and Iceland, cancer medicines are distributed either via hospitals and hospital pharmacies for inpatient use or via community pharmacies for outpatient use [2]. In Denmark, distribution of cancer medicines primarily occurs via publicly funded hospitals [2]. However, alongside the increasing costs of cancer care, a shift from inpatient to outpatient care has been observed [64,65].

1.5.2 Decision making on cancer medicines in Finland

Finland has generally had the most decentralized structure from all Nordic countries, as publicly funded healthcare in Finland was historically organised by over 300 municipalities [51,56]. Since 2023, these responsibilities have been transferred to 21 well-being services counties [51]. This decentralized structure shapes how new medicines are introduced in Finland, as manufacturers must navigate multiple assessment and decision-making bodies before medicines reach patients.

In Finland, the evaluation and decision-making system for medicines is multi-channel, with separate pathways for inpatient and outpatient medicines, each assessed through distinct processes and by different authorities, described more in detail below. HTA of new hospital-used medicines is conducted by the Finnish Medicines Agency (Fimea) and the Council for Choices in Healthcare (COHERE), which operates under the Ministry of Social Affairs and Health (Figure 3). For outpatient medicines, decisions on reimbursement and reasonable wholesale pricing are made by the Pharmaceuticals Pricing Board (PPB) based on HTA dossiers conducted by MA holder (Figure 4). [66]

Inpatient medicines

Fimea is responsible for the HTA of inpatient medicines [67]. According to the Act on the Finnish Medicines Agency (593/2009), one of Fimea's central tasks is to produce and compile assessments of the therapeutic and economic value of medicinal treatments and to coordinate related cooperation [68]. The HTA is produced with the goal that the assessment report becomes available as soon as possible after granting of MA [69].

The HTA process of inpatient medicines can be either authority-initiated or company-initiated. In the authority-initiated HTA process, Fimea monitors opinions issued by the EMA's Committee for Medicinal Products for Human Use (CHMP) regarding applications for MA. Following a positive CHMP opinion, Fimea decides whether to initiate a HTA for the medicine, and requests relevant information from the company (e.g. clinical trial data, subgroup analyses, treatment duration, costs, patient numbers in Finland, budget impact, and cost-effectiveness analyses). In the company-initiated process, the company notifies Fimea of the new medicine, planned submission date, and proposed assessment scope, which Fimea reviews before the formal application. Once either of the processes begins, it proceeds largely the same way: Fimea prepares a draft report based on available evidence, supported by FinCCHTA (Finnish Coordinating Center for Health Technology Assessment) and clinical experts, who provide guidance, and regional and clinical perspectives, and evaluate relevance to current practice. The HTA conducted by Fimea typically takes 3–4 months.[69]

The complete HTA report made by Fimea is submitted to the COHERE, which, according to Section 78 a of the Finnish Health Care Act (1326/2009), monitor and evaluate the health care service selection and make recommendations on whether health and medical care procedures, research, and treatment and rehabilitation methods should be included in the service selection or excluded from it [70]. In practice, subcommittee of COHERE together with secretariat drafts the recommendation based on scientific, clinical, ethical, organizational, and economic considerations, after which it undergoes public consultation before final approval and publication [71]. Recommendations can be positive, conditionally positive, or negative and may be permanent or time-limited [71]. The total assessment made by COHERE lasts typically 6 months [66]. After a conditionally positive recommendation, national price negotiations take place between the MA holder and the hospital procurement consortium, represented by Helsinki University Hospital (HUS) Pharmacy [66]. The national drug negotiation typically lasts from a few weeks up to several months [66].

After COHERE's national recommendation is published and the price is agreed, responsibility for the implementation of recommendation shifts to healthcare providers [71]. Implementation may involve primary care, specialized care, or both, and is easier when recommendations align with existing regional processes [71]. In contrast, those that require additional training or resources demand formal decisions to support their implementation [71]. For new cancer medicines, each regional medical director confirms the recommendation, and individual hospitals then decide on its uptake [51]. Approval at one hospital usually leads to quick adoption elsewhere, although availability of inpatient cancer medicines can still slightly vary across regions in Finland [51].

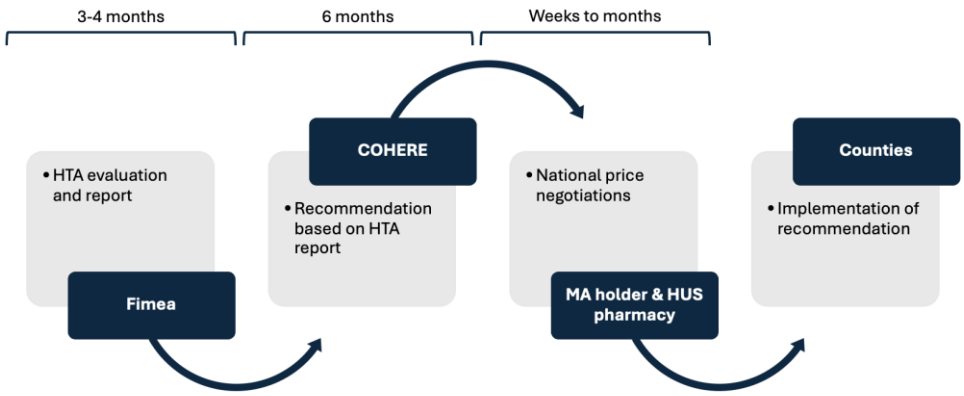

Figure 3. The assessment pathway for inpatient medicines in Finland. (HTA = Health Technology Assessment, COHERE = Council for Choices in Healthcare, MA = Marketing Authorization, HUS = Helsinki University Hospital)

Outpatient medicines

PPB operating under the Ministry of Social Affairs and Health deals with outpatient medicines [67]. According to the Health Insurance Act (1224/2004), PPB is responsible for confirming the reimbursement status and reasonable wholesale price of medicines, clinical nutritional products, and basic creams, deciding on increases to the wholesale price, and determining the discontinuation of reimbursement and wholesale prices [72]. A medicine with MA may be marketed without an approved wholesale price, but in such cases, it will not qualify for reimbursement and patients pay the entire cost of the medicine themselves [67].

The therapeutic value (reimbursement status) and the economic value (reasonable wholesale price) of medicines are assessed simultaneously [66]. The assessment is initiated upon application by the MA holder and is based on the materials submitted by the MA holder (e.g. the product's clinical effectiveness, economic value, and relevant regulatory status) [66,73]. Additionally, the assessment requires information provided under the HTA regulation [66]. During the review process, PPB may seek opinions from the Social Insurance Institution of Finland (Kela) and the medical expert group of the PPB [66]. Other stakeholders, including patient organizations, may also submit statements voluntarily [66].

Based on the Health Insurance Act (1224/2004), PPB is required to decide on an application for price and reimbursement within 180 days of receiving it [72]. PPB decisions apply nationwide and are binding on Kela in the implementation of the pharmaceutical reimbursement system [66]. Negotiations typically take 2–3 months, and implementation follows within two months of the decision [66].

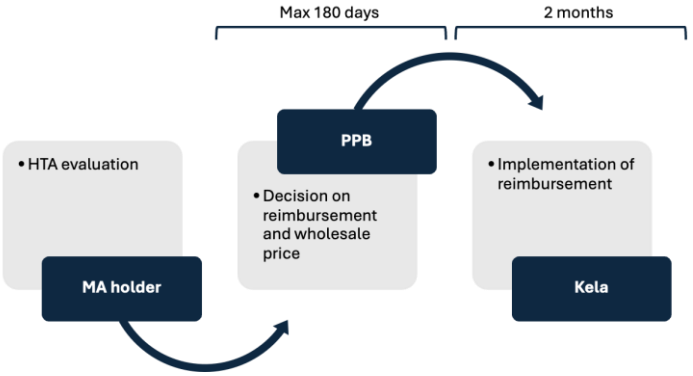

Figure 4. The assessment pathway for outpatient medicines in Finland. (HTA = Health Technology Assessment, MA = Marketing Authorization, PPB = Pharmaceuticals Pricing Board, Kela = Social Insurance Institution of Finland)

A key challenge of the Finnish HTA system is its fragmentation. The separation of assessment pathways for outpatient and hospital medicines may create a complex landscape for pharmaceutical companies, prescribers, and patients [66]. In addition, the evaluation of hospital medicines involves both national bodies (Fimea and COHERE) and regional decision-making by well-being services counties. This structure may lead to challenges in ensuring coordinated decision-making and may risk overlooking the broader system-level impacts of reimbursement and adoption decisions [66].

1.5.3 Decision making on cancer medicines in other Nordic countries

As described above, Finland has separate and complicated pathways for hospital-used and outpatient cancer medicines. To understand how this compares with other Nordic countries, the following sections give brief, country-specific overviews of how new cancer medicines are assessed, reimbursed, and implemented in Sweden, Norway, Denmark, and Iceland.

Sweden

The Swedish healthcare system is also relatively decentralized and provided through 21 counties [74]. Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU) performs at national level and evaluates health care and social service interventions from a comprehensive perspective, including medical, economic, ethical, and social considerations [75]. It chairs national HTA network including representatives from government agencies, such as the Dental and Pharmaceutical Benefits Agency (TLV), regional and local health technology assessment units, and other organizations involved in medical evaluation [75].

HTA in Sweden is mainly produced by SBU and TLV. HTA assessments performed by TLV aims to support decisions both on pricing and reimbursement of outpatient medicines, as well as on recommendations for inpatient medicines. For outpatient medicines, TLV decides whether the medicine

should be reimbursed. For inpatient medicines, the New Therapies Council (NTC) issues national recommendations based on TLV's HTA evaluations, while regional healthcare authorities make the final decisions on implementation, like in Finland. Thus, TLV's assessments and NTC's recommendations serve as guidance and do not automatically result in implementation at the regional level. [76]

Norway

Norway's healthcare structure is more centralised. The country has four regional health authorities, which are responsible for specialised healthcare, including cancer care, and participate in national decision-making [74,77]. This national level system in Norway, "Nye metoder" ("New methods"), manages the introduction of medicines for inpatient use through its "Beslutningsforum" ("Decision forum"), which make the final decision on inclusion of the medicine into hospital care [77]. The decisions at national level are based on the HTA made by Norwegian Medicines Agency (NOMA) [78]. NOMA also assesses whether medicines should be reimbursed in outpatient use [79].

Denmark

Denmark's healthcare structure is also more centralised as the country has five regional levels [74]. In Denmark, the Danish Medicines Council (DMC) evaluates the clinical and economic value of new drugs for hospital sector [80]. Once the HTA of a new medicine has been completed by DMC, a publicly owned organization Amgros negotiates the price with the manufacturer based on the assessment [81]. After the price is agreed, DMC decides at national level whether new drugs should be recommended for standard treatment in hospitals [81]. HTA evaluation process for outpatient medicines is separate and made by Danish Medicines Agency (DKMA) [82]. However, in Denmark, cancer medicines are primarily distributed via hospitals for inpatient use [2].

Iceland

The Icelandic healthcare system is highly centralized, although the country has seven regional levels whose administrative authority is limited [74]. According to Medicinal Products Act (100/2020) in Iceland, the Icelandic Medicines Agency (IMA) is responsible for the evaluation of medicinal products. Based on these evaluations, the IMA also makes decisions related to pricing, reimbursement, and uptake of medicines.

1.6 Aims and hypotheses

The aim of this study was to evaluate the association between clinical trial activity and post-marketing access to new cancer medicines in Finland and other Nordic countries. The study addressed the following research questions:

1. How does clinical trial activity of new cancer medicines vary across the Nordic countries?
2. How does post-marketing access to new cancer medicines differ between the Nordic countries?
3. Is clinical trial activity associated with post-marketing access to new cancer medicines?
4. How does Finland compare with other Nordic countries in terms of clinical trial activity and post-marketing access to new cancer medicines?

Based on the literature and theoretical considerations, the study hypothesized as follows:

1. Higher national clinical trial activity is associated with greater post-marketing access to new cancer medicines in the Nordic countries.
2. Finland exhibits lower clinical trial activity and weaker post-marketing access compared to other Nordic countries.

1.7 Conceptual framework

This study focused on the relationship between clinical trial activity and post-marketing access to new cancer medicines. As timely access ultimately aims to improve cancer outcomes, these outcomes provided an important context for this analysis. Clinical trial activity and access to new therapies can be viewed as interconnected components within a broader, multifactorial system shaping cancer outcomes. However, this study did not aim to assess the impact of these factors on outcomes directly. Instead, it adopted a conceptual framework to illustrate how clinical trial activity and access to new cancer medicines may be linked within the overall pathway from innovation to patient benefit.

In this context, understanding the current cancer burden in the Nordic countries was relevant for the purpose of this study. Nordic countries perform well in cancer care, with some of the highest cancer survival rates in Europe and worldwide [3,4]. Despite increasing cancer incidence, mortality rates have remained stable or even declined over time [2]. However, country-specific differences in cancer incidence and mortality persist across the region. Finland, for example, has demonstrated comparatively weaker outcomes in certain cancers, including lung cancer, non-Hodgkin lymphoma, myeloma, and chronic lymphocytic leukaemia [18]. Cancer outcomes are influenced by multiple factors, including stage at diagnosis and treatment patterns, which are likely to vary between Nordic countries [18]. In this context, access to new cancer medicines represents one component within a broader system influencing cancer outcomes.

As a summary from previous chapters, access to new cancer medicines is conceptualized as a multidimensional construct comprising availability, affordability, and accessibility, reflecting different stages from regulatory approval to patient use [1]. In this pathway (Figure 5), clinical trial activity plays a

role by contributing to evidence generation and strengthening clinical expertise within healthcare systems through early access to innovative therapies [6,10–12]. The evidence generated in clinical trials is critical for regulatory and reimbursement/funding decisions, while uncertainty in clinical evidence, which is common in oncology, may delay or limit access [35]. In addition, participation in clinical trials may facilitate the adoption of new therapies in clinical practice by increasing familiarity among healthcare professionals [10,38].

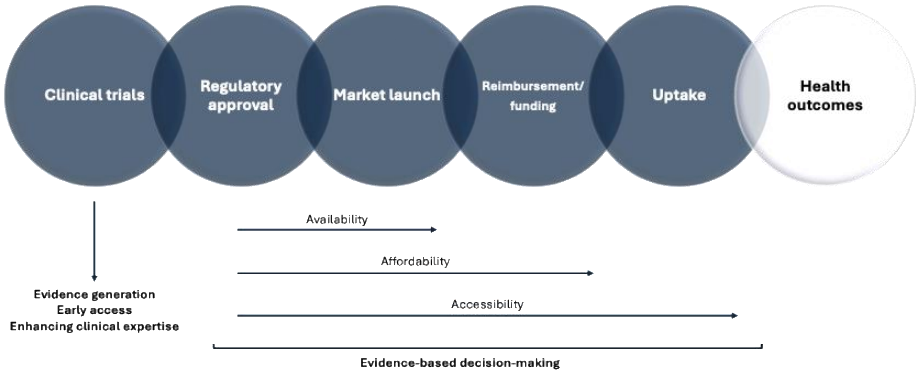

Figure 5. Conceptual framework: link between clinical trials, access to medicines, and health outcomes.

Despite these conceptual links, empirical evidence directly examining the relationship between clinical trial activity and post-marketing access to cancer medicines remains limited. Understanding this relationship is important for improving access to new treatments and, ultimately, for supporting better cancer outcomes. Therefore, further research is needed to clarify the role of clinical trial activity in shaping post-marketing access to cancer medicines within different healthcare systems.

2 Data and methods

2.1 Study design and data sources

This was a 10-year retrospective, observational and comparative study using data at the EU and Nordic levels from 2015 to 2024 with special focus on the post-marketing access to new cancer medicines in the Nordic countries. Multiple publicly available data sources were used at the EU and Nordic level (see Appendix 1 for links), complemented with commercial IQVIA first sales data. All data were obtained between September 2025 and March 2026.

Data on clinical trial activity were obtained from two different registries due to the transition to EU Clinical Trials Regulation (EU CTR) on 31 January 2022. These registries included Clinical Trials Register (CTR) and Clinical Trials Information System (CTIS). Information on cancer drug approvals were sourced from EMA and on the post-marketing access from the national regulatory and administrative agencies: Finnish Medicines Agency (Fimea), Dental and Pharmaceutical Benefits Agency (TLV), the New Therapies Council (NTC), Norwegian Medical Products Agency (NOMA), Danish Medicines Agency (DKMA), and Icelandic Medicines Agency (IMA). In addition, IQVIA first sales data were used to identify the timing of first sales registrations for new cancer medicines in Finland and Sweden.

2.2 Identification of new cancer medicines and EMA approvals

New cancer medicines were identified during the clinical trial search from the registered clinical trials in EU. Each cancer medicine, with a therapeutic intent, identified in clinical trials was subsequently linked to the EMA's database using the international non-proprietary name (INN) or product name to determine the date of MA. MA dates were obtained from the EMA's *"medicines from human use".* Medicines that received their initial MA in 2015 or later were classified as new cancer medicines. Consequently, medicines that were approved prior to 2015 were excluded from the study.

2.3 Assessment of clinical trial activity

Clinical trial activity in oncology was defined as the annual number of registered phase III (including phase II/III and phase III/IV) interventional oncology clinical trials per country. Additionally, clinical trial activity per each EMA approved cancer medicine was calculated across countries. The study covered clinical trials initiated between 1 January 2015 and 31 December 2024 that investigated new cancer medicines, as defined in chapter 4.2. The inclusion of phase III, phase II/III, and phase III/IV

trials were based on the study's aim to capture clinical trial activity most relevant to post-marketing access to new cancer medicines.

Clinical trials were retrieved from CTR for registrations before 31 January 2022, and from CTIS for trials registered thereafter. As registrations could be submitted to either registry between 1 February 2022 and 31 January 2023, additional searches were conducted for this period to ensure that all trials registered in CTR were included. Clinical trials were identified using the following search filters in both registries: condition (cancer), country (Finland, Sweden, Norway, Denmark, and Iceland), study type (interventional), and trial phase (phase III, II/III, III/IV). Searches were conducted separately for each year between 2015 and 2024 based on the trial start date. Transitioned trials from CTR to CTIS were calculated only once and duplicates were removed. Additionally, in CTR the "phase III" filter automatically included phase II/III and phase III/IV trials, whereas in CTIS phases were filtered separately.

Trial status classifications between the two registries slightly differed. For the clinical trials initiated before the transition, included trial statuses were *"completed"*, *"ongoing"*, *"prematurely ended"*, *"restarted"*, *"suspended by CA (Competent Authority)"*, *"temporarily halted" and "trial now transitioned"*. Excluded trial statuses were *"not authorised"* and *"prohibited by CA"*. For the clinical trials initiated after the transition, included trial statuses were *"authorised, recruitment pending"*, *"authorised, recruiting"*, *"ongoing, recruiting"*, *"ongoing, recruitment ended"*, *"temporarily halted"*, *"suspended"* and *"ended"*. Excluded trial statuses were *"expired"*, *"revoked"*, *"not authorised"* and *"cancelled"*. Inclusion and exclusion of certain clinical trial statuses ensured inclusion of only authorised trials with a genuine likelihood of implementation.

2.4 Assessment of post-marketing access

Post-marketing access

In this study, post-marketing access refers to the access to cancer medicines following the granting of MA by EMA. Post-marketing access to new cancer medicines was initially intended to be assessed using a uniform measure across all Nordic countries. However, during data collection it became evident that comparable data were not consistently available across countries. Therefore, post-marketing access was operationalized using three complementary dimensions: market entry, reimbursement/recommendation, and first sales, reflecting different stages in the pathway from regulatory approval to patient use. After identifying EMA approval dates for the medicines using the EMA's database, searches for post-marketing access dates were conducted using the INN or product name. If multiple dates were available for a medicine, the earliest date was included in the analysis.

Data on market entry in Finland were collected using Fimea's *"medicine search"*. According to Fimea's definition, a medicine is considered to be on the market when it is released for distribution and is available for use. For Norway, the market entry dates were obtained using the NOMA's *"medicine database"*. The date recorded in NOMA corresponds to the date when the medicine becomes available for distribution and patient use in Norway. For Iceland, market entry was determined using the IMA's *"human medicinal products with MA"*. Medicines listed as available were considered available for patients. For these available medicines, the date of market entry was obtained from IMA's *"icelandic medicine price catalogue"*, which records the date for first price registration for the medicine. Sweden does not offer a public database providing dates for market entry, comparable to those available in Finland, Norway, and Iceland. For Denmark, market entry of EMA approved cancer medicines was assessed using a list of medicines marketed in Denmark provided by DKMA. The list provided the status of the medicines in the market but did not include the dates for market entry.

Data on reimbursement/recommendation were available in Sweden. Reimbursed outpatient medicines were identified from the TLV's *"prices and decisions database"* which contains all reimbursed pharmaceuticals in Sweden and date for reimbursement. Inpatient medicines were identified from the NTC's *"archived recommendations"* which covers all medicines recommended for inpatient use in Sweden and dates for recommendation.

Data on the first sales registration of new cancer medicines were able to be obtained for Finland and Sweden from IQVIA and were used as a proxy for real-world uptake of new cancer medicines. Searches were conducted using the Anatomical Therapeutic Chemical (ATC) classification system. The ATC code corresponding to each medicine's first approved indication was used to identify the timing of first sales in the country.

Time to access

Time to access of new cancer medicines was defined as the time delay between the EMA's MA date and the date of market entry, reimbursement/recommendation, or first sales. For each medicine and country, delays for market entry and reimbursement/recommendation were calculated as the number of days between the EMA's MA date and the date of market entry or reimbursement/recommendation. To facilitate comparability across countries and over time, delays were converted from days to months.

In the IQVIA data, the timing of first sales was reported with a precision of one month. To determine the access delay, the first sales date was set to the last day of the reported month. The delay was then calculated in days between the EMA approval date and the adjusted first sales date, and subsequently converted into months.

As publicly available information on market entry dates was not available in Denmark, time to availability could not be calculated for Denmark. Consequently, Denmark was excluded from analyses involving access delays. The overall study design is illustrated in the Figure 6 below.

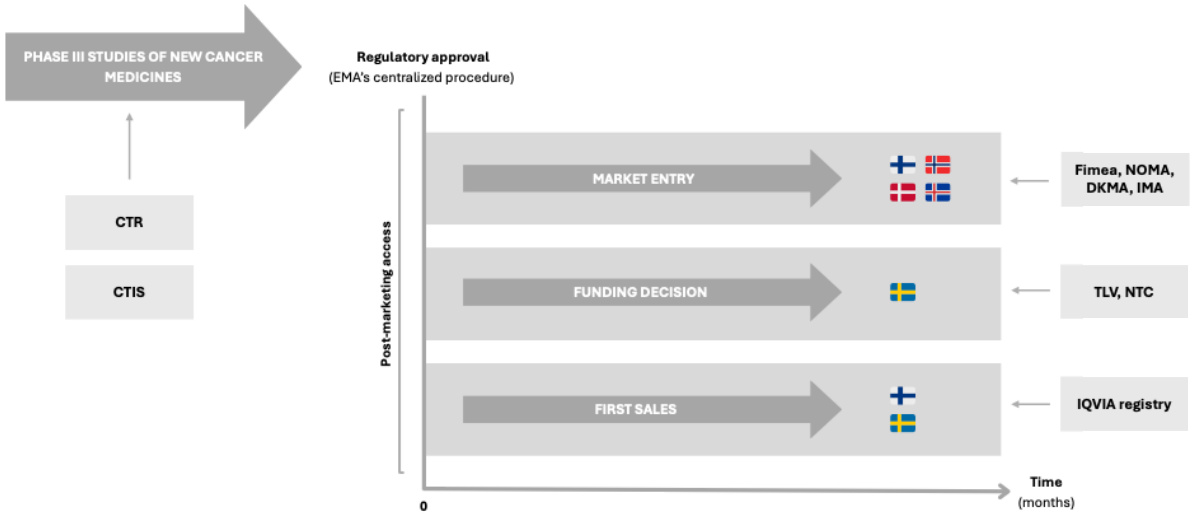

Figure 6. Study design. This retrospective study assessed phase III clinical trial activity of new cancer medicines and its association to their post-marketing access across the Nordic countries using three different access dimensions: market entry, reimbursement/recommendation, and first sales registration. Time to access was defined as the delay between EMA approval and each access dimension. Market entry data were available for Finland, Norway, Iceland, and Denmark, although the date of market entry was not available for Denmark. Data on funding decision were available for Sweden, and first sales data for Finland and Sweden. The study used both publicly available EU and Nordic level data sources and commercial IQVIA first sales registry. In this study, cancer medicines with therapeutic intent, that received their initial marketing authorization in 2015 or later, were classified as new cancer medicines. (CTR = Clinical Trials Register, CTIS = Clinical Trials Information System, DKMA = Danish Medicines Agency, Fimea = Finnish Medicines Agency, IMA = Icelandic Medicines Agency, NOMA = Norwegian Medical Products Agency, NTC = New Therapies Council, TLV = Dental and Pharmaceutical Benefits Agency)

2.5 Statistical analysis

The statistical approach was mainly descriptive due to the non-causal and complex nature of the study design and factors involving it. Descriptive statistics, including counts, proportions, means, medians, standard deviations (SDs), and interquartile ranges (IQRs) were used to summarise clinical trial activity, access to cancer medicines, and time to access across countries. A non-parametric Mann-Whitney U test was conducted to compare time to first sales between Finland and Sweden.

The association between clinical trial activity and post-marketing access to new cancer medicines was assessed descriptively. The total number of clinical trials of EMA approved medicines was compared with the total number of available medicines and mean access delays across countries and across the three access dimensions (market entry, reimbursement/recommendation, first sales). Additionally,

association was examined based on drug-level clinical trial activity, where the proportion of available medicines was calculated for following three categories: EMA approved medicines with 0, 1, and ≥2 trials. All descriptive analyses were performed using Microsoft Excel for Mac (Version 16.83), while the Mann-Whitney U test was conducted using RStudio (Version 2025.05.1+513).

2.6 Ethical considerations

The study did not include any individual-level or identifiable personal data, nor were such data collected, accessed, or processed at any stage. Given the non-interventional nature of the study and the absence of personal data, ethical approval by an ethics committee was not required.

Use of Artificial Intelligence Tools

Artificial intelligence tools were used in the preparation of this thesis to assist with improving the language quality of the text. The author takes full responsibility for the content and academic integrity of the thesis.

3 Results

3.1 Clinical trial activity of new cancer medicines in the Nordic countries

Phase III clinical trials (including phase II/III and phase III/IV) investigating new cancer medicines were identified and analyzed country-by-country. Phase II/III and phase III/IV trials were not analyzed separately due to their small number and were therefore included in the phase III trial category. Figure 7 presents the annual number of phase III clinical trial initiations of new cancer medicines in each Nordic country. The number of phase III clinical trial initiations across countries is presented in detail in Appendix 3.

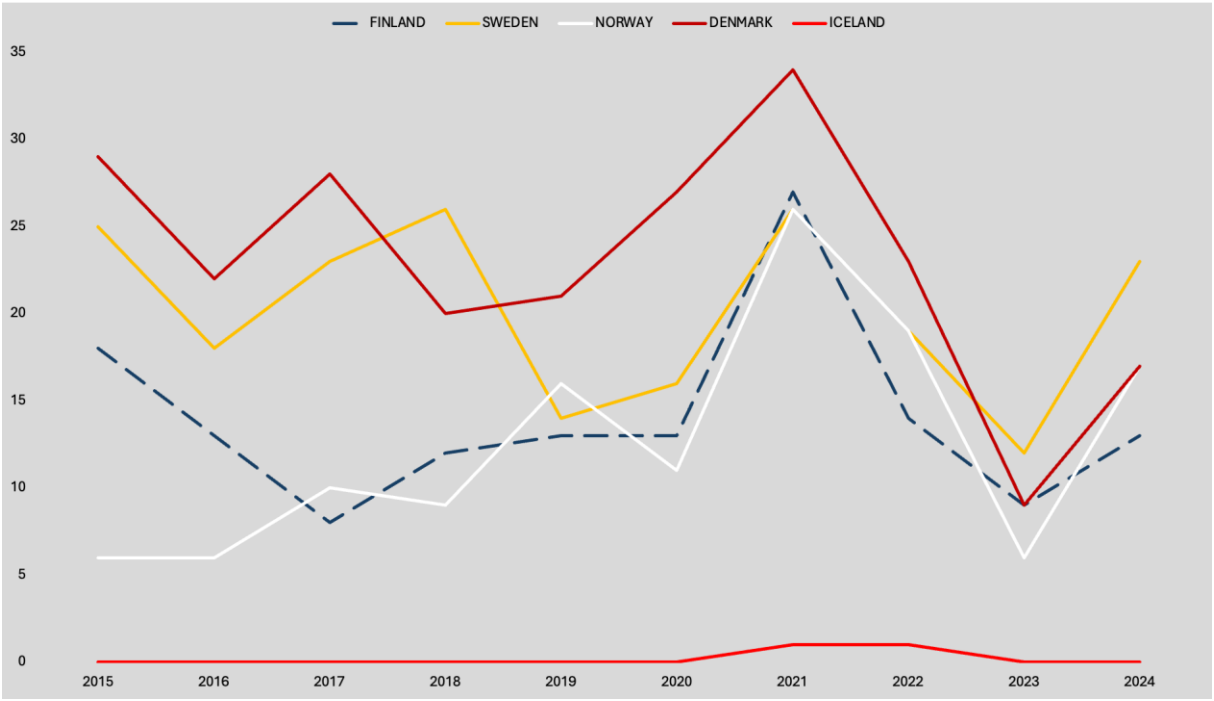

Figure 7. Phase III clinical trial initiations (including phase II/III and III/IV) of new cancer medicines across the Nordic countries in 2015-2024.

The annual number of trials fluctuated over time both between and within countries. In Finland, the annual number of initiated trials ranged from 8 to 27 during the study period. Similar ranges were observed in Sweden and Norway, where annual trial numbers varied between 12 and 26 (Sweden) and between 6 and 26 (Norway), respectively. Denmark generally reported higher annual numbers, ranging from 9 to 34 trials. Only two study starts were observed in Iceland (in 2021 and 2022).

The total clinical trial activity varied across the Nordic countries during the study period. A total of 140 phase III oncology clinical trials were initiated in Finland. This was fewer than in Denmark (230) and

Sweden (202), but slightly more than in Norway (126). In contrast, for Iceland, only two trials were identified, demonstrating minimal clinical trial activity in Iceland compared to other Nordic countries.

While the number of initiated clinical trials varied across Nordic countries, overall trends in trial activity were similar between countries (except for Iceland). As shown in Figure 7, clinical trial activity increased sharply in 2021, reaching a peak in annual trial initiations across the Nordic region. Following this peak, the number of initiated trials declined markedly between 2021 and 2023.

In addition to annual clinical trial initiations per country, the drug-level clinical trial activity across countries was identified (see Appendix 4). Table 1 shows the number of EMA approved medicines that were investigated in 0, 1, or ≥2 phase III clinical trials across the Nordic countries. In Finland, nearly half of the EMA approved cancer medicines (48%) were not investigated in any phase III trials, like in Norway (46%). In contrast, Sweden and Denmark demonstrated higher drug-level trial activity overall: only 19% of EMA approved medicines in Sweden and 25% in Denmark had no trial involvement, indicating that most drugs were studied in at least one trial. In Iceland, majority of drugs (98%) was not tested in phase III trials at all. Moreover, a larger share of EMA approved cancer medicines was studied in two or more trials in Sweden (40%), Denmark (43%), and Norway (28%) than in Finland (23%).

Table 1. The number of EMA approved cancer medicines investigated in 0 trials, 1 trial or ≥ 2 trials across the Nordic countries.

	The number of EMA approved medicines, n (%)				
Trials per medicine	**Finland**	**Sweden**	**Norway**	**Denmark**	**Iceland**
0 trials	40 (48)	16 (19)	38 (46)	21 (25)	81 (98)
1 trial	24 (29)	34 (41)	22 (27)	26 (31)	2 (2)
≥2 trials	19 (23)	33 (40)	23 (28)	36 (43)	-

3.2 Post-marketing access and time to access in the Nordic countries

This section examines the post-marketing access and time to access of EMA approved cancer medicines in the Nordic countries. Detailed results are provided in Appendices 5-9. The total of 83 EMA approved cancer medicines were identified and included in the analyses. Of these, 17% received conditional MA, and 25% were assigned with orphan status. Details of all EMA approved medicines included in the study are presented in Appendix 2.

According to the data on market entry, Finland demonstrated slightly lower post-marketing access with 61 medicines (73%) compared to Norway's 65 medicines (78%) and Denmark's 66 medicines (80%).

Access was also lower in Finland than in Sweden based on the data on IQVIA first sales, with 53 medicines (64%) recorded in Finland and 61 medicines (73%) in Sweden. Iceland showed clearly lower access according to the market entry data with 48 medicines (58%) compared to the other Nordic countries. In Sweden, 64 medicines (77%) were either reimbursed or recommended for use. Within the countries (Finland and Sweden), the number of medicines reaching first sales tended to be lower than those registered to be on the market (Finland) or reimbursed/recommended (Sweden). Overall, differences in the number available medicines across the access dimensions were generally modest across countries, except for Iceland. (Table 2)

Table 2. The number of available medicines and time to access in months based on different access dimensions across the Nordic countries.

Access dimension	***Country***	**Available medicines, n (%)**	**Access delay, mean (SD)**	**Access delay, median (IQR)**
Market entry	*Finland*	61 (73)	10 (16)	4 (2-12)
	Norway	65 (78)	8 (12)	4 (3-9)
	Denmark	66 (80)	N/A	N/A
	Iceland	48 (58)	20 (16)	16 (9-26)
Reimbursement/Recommendation	*Sweden*	64 (77)	14 (18)	7 (4-17)
IQVIA first sales	*Finland*	53 (64)	7 (9)	3 (2-8)
	Sweden	61 (73)	7 (12)	3 (2-5)

Median time to market entry was 4 months in both Finland and Norway. However, Finland showed a slightly longer mean delay (10 months) compared with Norway (8 months). No difference in mean or median delay was observed between Finland and Sweden based on IQVIA first sales data, where both countries showed a mean delay of 7 months and a median delay of 3 months. This was confirmed with a non-parametric Mann-Whitney U test, which showed non-significant difference in time to first sales between Finland and Sweden (W=1862, p-value=0.164). Iceland showed a markedly longer mean delay to market entry (20 months) compared with Finland and Norway, with a median of 16 months. In Sweden, the mean delay to reimbursement/recommendation was 14 months, with a median of 7 months. When comparing different access dimensions, time to first sales was generally shorter than time to market entry or reimbursement/recommendation. Overall, median access delays were consistently lower than mean access delays across countries, and differences in mean and median access delays between countries were generally minimal, with Iceland again representing an exception.

Relatively high SDs were observed across countries, indicating substantial variability in access delays within country. Finland and Iceland showed greater SDs (16 months) compared with Norway (12 months) regarding market entry. On the other hand, for first sales, lower SD was identified for Finland (9 months) compared with Sweden (12 months). The IQRs further confirmed considerable within-country variability in access delays. Finland demonstrated wider IQR (2-12 months) compared with Norway (3-9 months) regarding market entry, meanwhile Iceland demonstrated even wider IQR (9-26 months). Additionally, for first sales, Finland showed greater IQR (2-8 months) compared with Sweden (2-5 months).

3.3 Association between clinical trial activity and post-marketing access

When combining the results from the chapter 5.1 (clinical trial activity) and 5.2 (post-marketing access), no consistent association was observed between total clinical trial activity and post-marketing access or access delay across countries. While Denmark showed the highest number of total trials (230) and the highest number of medicines on the market (66), and Iceland had the lowest number of trials (2) and the lowest number of medicines on the market (48), for Finland and Norway the association was not as unequivocal. In Finland, the number of total trials was greater (140) than in Norway (126), but Norway showed greater number of medicines on the market (65) and shorter mean access delay (8 months) compared with Finland's 61 medicines and 10 months mean access delay. Based on IQVIA first sales data, the association between total trials and available medicines seemed to be unequivocal but the comparison was based solely on Finland and Sweden.

The association between drug-level clinical trial activity and post-marketing access is shown in Table 3. Across most countries, the proportion of available medicines increased with the number of clinical trials per medicine. Medicines with no trials generally showed the lowest percentual post-marketing access, whereas medicines investigated in two or more trials showed the highest percentual access.

In Finland based on market entry data, 58% of EMA approved cancer medicines with no trials were available, compared with 79% of medicines with one trial and 100% of medicines investigated in two or more trials. A similar pattern was observed in Norway and Denmark, where medicines involved in a greater number of trials tended to be more likely on the market. Additionally, a comparable pattern was observed when access was defined using reimbursement/recommendation data for Sweden and IQVIA first sales data for Finland and Sweden. However, proportions seemed to be slightly lower on average, especially when comparing first sales with market entry. Iceland was an exception, as 58% of EMA approved medicines with no trials was on the market and 50% of medicines with 1 trial was on the market; however, this pattern should be interpreted with caution due to the very limited number of clinical trials in Iceland.

Table 3. The number of available medicines by drug-level clinical trial activity.

		The number of available medicines, n (%)		
Access dimension	***Country***	**0 trials**	**1 trial**	**≥2 trials**
Market entry	*Finland*	23 (58)	19 (79)	19 (100)
	Norway	25 (66)	19 (86)	21 (91)
	Denmark	13 (62)	20 (77)	33 (92)
	Iceland	47 (58)	1 (50)	-
Reimbursement/Recommendation	*Sweden*	11 (69)	24 (71)	29 (88)
IQVIA first sales	*Finland*	20 (50)	15 (63)	18 (95)
	Sweden	10 (63)	22 (65)	29 (88)

4 Discussion

This study describes trends in phase III oncology clinical trial activity (2015-2024) and examines access to new cancer medicines across the Nordic countries, providing an insight into the potential role of clinical trials in facilitating post-marketing access. Although the Nordic countries share broadly similar healthcare systems, differences exist in clinical trial activity, post-marketing access, and time to access of new cancer medicines. This study further demonstrates that cancer medicines with a higher number of phase III clinical trials in a country were more likely to be available in that country.

Clinical trial activity

Finland's moderate level of clinical trial activity observed in the study may partly reflect previously identified structural challenges, such as fragmented trial infrastructure and increasing global competition for clinical research [40]. Previous studies have also shown that Sweden, Denmark, and Norway rank among the top countries in Europe in terms of early-phase (phase I and II) single-country commercial trials [16]. Although the present study did not distinguish between single- and multi-country trials and focused on late-phase trials (phase III, phase II/III, phase III/IV), lower number of medicines with zero trials and higher number of medicines with multiple trials observed in these countries may reflect their overall stronger clinical trial activity. Even though Finland had slightly weaker drug-level activity compared with Norway, the total clinical trial activity was higher in Finland, highlighting differences in how trial activity is distributed across medicines.

Denmark appeared to have the highest total clinical trial activity, as expected. Clinical trial capabilities, such as faster trial start-up timelines and recruitment, have previously been reported to affect the conduction of clinical trials, and Denmark (together with Poland and Spain) has showed the fastest enrolment timelines within EEA, which may explain the high clinical trial performance in Denmark [16]. Additionally, Denmark's Trial Nation model seeks to create more efficient and cost-effective clinical research environments [40], making the country an attractive location for industry-sponsored trials, supporting the observed high trial activity. In contrast, Iceland exhibited minimal clinical trial activity during the study period. This limited activity may reflect the country's small population and more restricted capabilities to conduct clinical trials, which may constrain the initiation and conduct of clinical studies in Iceland.

Despite the observed differences in clinical trial activity between countries, the study found out that the overall trends were similar across countries during the study period. The remarkable increase in clinical trial activity observed in 2021 and following decrease in trial initiations between 2021-2023 within countries other than Iceland evoked special attention. This phenomenon may arise from the EU CTR implemented in 2022 and the new Clinical Trials Information System (CTIS) [41], which likely caused the

submission of trial applications under the previous and more familiar system before the new regulation took effect [41]. Additionally, COVID-19 may also be an explanatory factor as previously reported delays in trial initiation caused by the pandemic in 2020 [83] may have led to a rebound in 2021. The following downward trend may be explained by the delays in approval processes due to EU CTR introduced previously [40]. Despite the previously observed decrease in clinical trial activity within the EEA and the long-standing downward trend in Finland [10,16], no clear decreasing trend was observed within any country in the present study when considering the whole study period. This may partly reflect the inclusion of only phase III studies, whereas the decline at the EEA level has been primarily driven by reductions in phase I trials [16].

Post-marketing access and time to access

According to the findings, post-marketing access to cancer medicines varied across the Nordic countries both in terms of the number of available medicines and access delay, which was expected, as previous studies have demonstrated cross-country differences in access and time to access [1,6,15]. While differences in the number of available medicines as well as mean and median access delays were generally modest or even minimal across the Nordic countries, greater variation was observed in the spread of access delays between countries, as reflected by differences in SDs and IQRs. Differences in within-country variation in access delays may partly reflect differences in evidentiary requirements and benefit-risk assessments at the time of market entry across countries.

Compared with Denmark and Norway, Finland showed slightly lower number of medicines on the market, as well as longer mean access delays and greater variability in access delays than Norway. This may reflect previously reported complexities in the Finnish pricing and reimbursement system [66]. In addition, earlier studies have suggested that factors such as greater pricing flexibility and the timing of economic evaluations in relation to regulatory approval can influence the speed of market entry [14]. Further, Norway has been reported to move towards more centralized healthcare structure [63], supporting the shorter access delay and lower variability in them. Moreover, while no statistically significant difference in access delays to first sales was observed between Finland and Sweden, Finland showed a lower number of available medicines and greater variability in access delays (measured as IQR) based on first sales. This may further reflect the challenges in the Finnish healthcare system, despite the similarities in their decentralized healthcare systems, where regional authorities play a key role in decisions on medicine implementation. Iceland's remarkably longer access delay and greater variability based on market entry data, despite their centralized healthcare system, likely reflect smaller market size, as it has found to have an impact on company's launch strategy [45].

Given prior evidence suggesting that Finland lags behind other Nordic countries in the adoption of pharmaceutical innovations [17], especially within oncology, examining post-marketing access through

multiple dimensions provides a more nuanced understanding of where potential delays may occur. According to the study, the number of medicines available based on first sales data in Finland and Sweden was consistently lower than that based on market entry (Finland) or reimbursement/recommendation (Sweden), indicating that medicine being on the market or funding decision do not necessarily translate into actual use. It has been reported that in Finland, for example, uptake of cancer medicines is determined at the hospital level even after national recommendations, which may limit actual use [51], supporting the finding. Surprisingly, access delays based on sales data were shorter than those based on market entry or reimbursement/recommendation. This likely reflects that first sales data capture the earliest measurable signal of uptake ("real-world launch"), being the first observed commercial transaction in the distribution chain, while not reflecting the full extent of broader uptake. Overall, the access dimensions applied in this study do not fully capture real patient-level access, which remains difficult to measure [1]. Furthermore, lack of data and differences in reporting practices between countries complicated direct comparisons of post-marketing access and represent an important result of this study.

Association between clinical trial activity and post-marketing access

A central aim of this study was to explore whether clinical trial activity is associated with post-marketing access to new cancer medicines. The study found out, that post-marketing access increased with the number of clinical trials per medicine across most countries, suggesting that medicines investigated in more trials are more likely to be available. This may also reflect that medicines considered more promising or clinically important are more likely to be investigated in multiple trials and subsequently prioritized in access decisions. However, this finding should be interpreted with caution, as time may act as a confounding factor: medicines approved earlier have had more time both to accumulate clinical trials and to become available in national systems. In addition, the analysis did not distinguish between different indications within the same medicine. A single medicine may be investigated in multiple phase III trials across different indications, which may increase its overall trial count and may also increase the likelihood of it being used in at least one approved indication.

At the country level, no clear association was observed between total clinical trial activity and either post-marketing access or time to access. This suggests that overall trial volume alone does not directly translate into broader or faster access, and that system-level factors, such as funding decisions and implementation processes, may play a more decisive role in post-marketing access to medicines when it comes to total access at national level. Additionally, total trial volume does not account for how trials are distributed across medicines, and as they may be concentrated on a limited number of medicines, this can result in a positive association at the drug-level without translating into broader access when assessed using total activity.

However, previous research has suggested that participation in clinical trials may enhance familiarity with new treatments and support their use in clinical practice [10,38]. This potential effect might explain the higher number of medicines available in Sweden compared with Finland based on first sales data, as Sweden showed clearly higher total trial activity. However, this comparison was solely based on Sweden and Finland and needs to be considered with caution. On the other hand, the effect of clinical trials in smoother adoption may explain the finding that Norway demonstrated higher total number of new cancer medicines on the market than Finland despite the lower total number of trials as wider range of medicines were studied in Norway than in Finland.

Overall, the relationship between clinical trial activity and post-marketing access should be interpreted cautiously, as no causal inferences can be drawn. Access to medicines is inherently multidimensional and influenced by several factors beyond the potential role of clinical trial activity, with the strength of clinical evidence, national funding capacity, and other system-level factors playing a particularly important role.

Strengths and limitations

This study has several strengths and limitations. While previous studies have examined trends in oncology clinical trial activity and disparities in access to cancer medicines separately, this study integrates these two key phenomena, representing an important contribution within real-world evidence research in oncology. In addition, whereas earlier studies have typically relied on a single access dimension (e.g. reimbursement), this study incorporates three complementary access measures (market entry, reimbursement/recommendation and first sales), thereby providing a more comprehensive perspective on the complexity of defining access to new cancer medicines as well as enabling identification of where potential bottlenecks in post-marketing access may occur across countries.

The multidimensional approach in access also introduces limitations, as differences in access dimensions and data availability between countries complicate cross-country comparisons. Furthermore, access was assessed using regulatory and administrative data, which do not fully capture actual patient-level access – obviously the most relevant dimension in terms of cancer outcomes. Regarding clinical trial activity, the inclusion of only phase III trials may limit the overall picture, although this choice was made to focus on trials most relevant to post-marketing access to new cancer medicines. Finally, due to its observational design, this study does not allow for causal inference, limiting the determination and interpretation of association between trial activity and post-marketing access to cancer medicines.

Key findings and current strategies

In summary, the results indicated variation in phase III clinical trial activity for new cancer medicines across the Nordic countries both in the total number of trials initiated and in their distribution across individual medicines. Post-marketing access to new cancer medicines also differed but the differences were generally modest. While higher clinical trial activity was associated with greater access at the drug-level, total trial volume at the country-level did not clearly correspond with overall access. The contribution of clinical trials and new cancer medicines to population-level cancer outcomes is likely limited, as many factors beyond access to novel innovations, including diagnosis and disease stage, also play a role.

As challenges and disparities in access to oncology clinical trials as well as in access to cancer medicines have long been recognized within healthcare systems, various initiatives have been launched to address these issues. Previously mentioned EU CTR is one of them as it aims to harmonize clinical research processes in Europe [41]. However, such measures take time, and their full impact may not yet be visible. In addition to EU-level efforts, national initiatives on research activities have also emerged. Denmark's Trial Nation model, along with comparable programs in Sweden (SweTrial) and Norway (NorTrial), have been developed to strengthen national collaboration in drug research [40]. Inspired by these, a FinTrials model has recently been proposed in Finland with similar objectives [40]. Moreover, the recently published Finnish Cancer Strategy (2026–2035) has outlined goals guided by values such as reducing inequality, improving quality of life, enhancing treatment effectiveness, and emphasizing the importance of research, with equity serving as a cross-cutting theme [84]. The findings from this study highlight the importance of both EU-wide and national strategies aimed at strengthening research activity and ensuring equitable access to new therapies.

Conclusions

In conclusion, this study indicates the interplay between clinical trial activity and post-marketing access to new cancer medicines, highlighting the association at drug-level and the impact of trial distribution across the medicines on overall access at country level. Differences in access dimensions and data availability complicate cross-country comparisons and achieving the real patient-level access. Overall, access to medicines is inherently multidimensional and shaped by structural, regulatory, and economic factors beyond the possible role of clinical trial activity. Thus, this study underscores the importance of clinical trial infrastructure and well-functioning healthcare system processes in supporting timely and equitable access to medicines and enhancing cancer outcomes. Together, these factors may also generate broader economic benefits for society. Future research would benefit from more consistent cross-country reporting and should focus on clarifying the role of clinical trials in enhancing post-marketing access and examining the association within specific indications to better understand the contribution of clinical trial activity to post-marketing access to new cancer medicines.

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References

(1) Chapman, S.; Paris, V.; Lopert, R. *Addressing Challenges in Access to Oncology Medicines*. OECD. https://www.oecd.org/en/publications/challenges-in-access-to-oncology-medicines_4b2e9cb9-en.html (accessed 2025-08-19).

(2) Sarnola, K.; Koskinen, H.; Klintrup, K.; Astrup, C.; Kurko, T. Uptake and Availability of New Outpatient Cancer Medicines in 2010–2021 in Nordic Countries – Survey of Competent Authorities. *BMC Health Serv. Res.* **2023**, *23* (1), 1437. https://doi.org/10.1186/s12913-023-10421-x.

(3) Hofmarcher, T.; Brådvik, G.; Svedman, C.; Lindgren, P.; Jönsson, B.; Wilking, N. *Comparator Report on Cancer in Europe 2019 – Disease Burden, Costs and Access to Medicines - IHE*. https://ihe.se/en/rapport/comparator-report-on-cancer-in-europe-2019/ (accessed 2025-08-12).

(4) Lundberg, F. E.; Andersson, T. M.-L.; Lambe, M.; Engholm, G.; Mørch, L. S.; Johannesen, T. B.; Virtanen, A.; Pettersson, D.; Ólafsdóttir, E. J.; Birgisson, H.; Johansson, A. L. V.; Lambert, P. C. Trends in Cancer Survival in the Nordic Countries 1990–2016: The NORDCAN Survival Studies. *Acta Oncol.* **2020**, *59* (11), 1266–1274. https://doi.org/10.1080/0284186X.2020.1822544.

(5) Elmadani, M.; Mokaya, P. O.; Omer, A. A. A.; Kiptulon, E. K.; Klara, S.; Orsolya, M. Cancer Burden in Europe: A Systematic Analysis of the GLOBOCAN Database (2022). *BMC Cancer* **2025**, *25* (1), 447. https://doi.org/10.1186/s12885-025-13862-1.

(6) Hofmarcher, T.; Berchet, C.; Dedet, G. *Access to oncology medicines in EU and OECD countries*. OECD. https://www.oecd.org/en/publications/access-to-oncology-medicines-in-eu-and-oecd-countries_c263c014-en.html (accessed 2025-05-13).

(7) IQVIA Oncology Link. *What is Behind the Robust Growth in the Global Oncology Market?* https://www.iqvia.com/library/articles/what-is-behind-the-robust-growth-in-the-global-oncology-market (accessed 2025-08-12).

(8) Page, D. B.; Postow, M. A.; Callahan, M. K.; Allison, J. P.; Wolchok, J. D. Immune Modulation in Cancer with Antibodies. *Annu. Rev. Med.* **2014**, *65* (Volume 65, 2014), 185–202. https://doi.org/10.1146/annurev-med-092012-112807.

(9) Carneiro, A.; Amaral, T. M. S.; Brandao, M.; Scheffler, M.; Bol, K.; Ferrara, R.; Jalving, M.; Russo, G. L.; Marquez-Rodas, I.; Matikas, A.; Mezquita, L.; Morgan, G.; Onesti, C. E.; Pilotto, S.; Saloustros, E.; Trapani, D. LBA66_PR Disparities in Access to Oncology Clinical Trials in Europe in the Period 2009-2019. *Ann. Oncol.* **2020**, *31*, S1196. https://doi.org/10.1016/j.annonc.2020.08.2301.

(10) *Lääketutkimuksen Arvo Yhteiskunnalle*; 2024. https://www.laaketeollisuus.fi/media/julkaisut/esitteita-ja-raportteja/laaketutkimuksen-yhteiskunnallinen-arvo-loppuraportti_verkkosivuille.pdf (accessed 2025-08-19).

(11) Naci, H.; Salcher-Konrad, M.; Kesselheim, A. S.; Wieseler, B.; Rochaix, L.; Redberg, R. F.; Salanti, G.; Jackson, E.; Garner, S.; Stroup, T. S.; Cipriani, A. Generating Comparative Evidence on New Drugs and Devices before Approval. *The Lancet* **2020**, *395* (10228), 986–997. https://doi.org/10.1016/S0140-6736(19)33178-2.

(12) Kehoe, L.; Locke, T.; McClellan, M.; Landray, M.; Hernandez, A.; Okun, S. Overcoming the Barriers to Better Evidence Generation from Clinical Trials. *Trials* **2024**, *25* (1), 614. https://doi.org/10.1186/s13063-024-08460-8.

(13) Büssgen, M.; Stargardt, T. Changes in Launch Delay and Availability of Pharmaceuticals in 30 European Markets over the Past Two Decades. *BMC Health Serv. Res.* **2022**, *22* (1), 1457. https://doi.org/10.1186/s12913-022-08866-7.

(14) Mulcahy, A. W. Comparing New Prescription Drug Availability and Launch Timing in the United States and Other OECD Countries. *Rand Health Q.* **2024**, *11* (3), 4.

(15) Li, M.; Ka, D.; Chen, Q. Disparities in Availability of New Cancer Drugs Worldwide: 1990-2022. *BMJ Glob. Health* **2024**, *9* (9). https://doi.org/10.1136/bmjgh-2024-015700.

(16) Europe, V. *Assessing the clinical trial ecosystem in Europe*. Vaccines Europe. https://www.vaccineseurope.eu/media-hub/publications/assessing-the-clinical-trial-ecosystem-in-europe/ (accessed 2026-02-20).

(17) Newton, M.; Stoddart, K.; Travaglio, M.; Troein, P. EFPIA Patients W.A.I.T. Indicator 2024 Survey.
(18) Hemminki, K.; Karihtala, P.; Hemminki, A. *Syöpien elossaoloennusteet jääneet jälkeen muista Pohjoismaista*. Lääkärilehti.fi. http://www.laakarilehti.fi/tieteessa/alkuperaistutkimukset/syopien-elossaoloennusteiden-kehitys-suomessa-ei-ole-pysynyt-muiden-pohjoismaiden-vauhdissa/?public=8b4dc95386949595c5d0a2598411aef8 (accessed 2025-08-12).
(19) *Clinical trials*. https://www.who.int/health-topics/clinical-trials (accessed 2026-02-17).
(20) Torres-Saavedra, P. A.; Winter, K. A. An Overview of Phase II Clinical Trial Designs. *Int. J. Radiat. Oncol. Biol. Phys.* **2022**, *112* (1), 22–29. https://doi.org/10.1016/j.ijrobp.2021.07.1700.
(21) Commissioner, O. of the. Step 3: Clinical Research. *FDA* **2025**.
(22) DeVita, V. T.; Lawrence, T. S.; Rosenberg, S. A. *DeVita, Hellman, and Rosenberg's Cancer: Principles & Practice of Oncology, 10e | Oncology | Health Library*.
(23) Kelly, W. K.; Halabi, S. *Oncology Clinical Trials: Successful Design, Conduct, and Analysis*; Springer Publishing Company, 2018.
(24) Friedman, L. M.; Furberg, C. D.; DeMets, D. L.; Reboussin, D. M.; Granger, C. B. *Fundamentals of Clinical Trials*; Springer International Publishing: Cham, 2015. https://doi.org/10.1007/978-3-319-18539-2.
(25) Green, S. B.; Byar, D. P. Using Observational Data from Registries to Compare Treatments: The Fallacy of Omnimetrics. *Stat. Med.* **1984**, *3* (4), 361–370. https://doi.org/10.1002/sim.4780030413.
(26) Baumfeld Andre, E.; Reynolds, R.; Caubel, P.; Azoulay, L.; Dreyer, N. A. Trial Designs Using Real-World Data: The Changing Landscape of the Regulatory Approval Process. *Pharmacoepidemiol. Drug Saf.* **2020**, *29* (10), 1201–1212. https://doi.org/10.1002/pds.4932.
(27) Naci, H.; Davis, C.; Savović, J.; Higgins, J. P. T.; Sterne, J. A. C.; Gyawali, B.; Romo-Sandoval, X.; Handley, N.; Booth, C. M. Design Characteristics, Risk of Bias, and Reporting of Randomised Controlled Trials Supporting Approvals of Cancer Drugs by European Medicines Agency, 2014-16: Cross Sectional Analysis. *BMJ* **2019**, *366*. https://doi.org/10.1136/bmj.l5221.
(28) Farina, A.; Moro, F.; Fasslrinner, F.; Sedghi, A.; Bromley, M.; Siepmann, T. Strength of Clinical Evidence Leading to Approval of Novel Cancer Medicines in Europe: A Systematic Review and Data Synthesis. *Pharmacol. Res. Perspect.* **2021**, *9* (4), e00816. https://doi.org/10.1002/prp2.816.
(29) Liu, I. T. T.; Kesselheim, A. S.; Cliff, E. R. S. Clinical Benefit and Regulatory Outcomes of Cancer Drugs Receiving Accelerated Approval. *JAMA* **2024**, *331* (17), 1471–1479. https://doi.org/10.1001/jama.2024.2396.
(30) DiMasi, J. A.; Grabowski, H. G. Economics of New Oncology Drug Development. *J. Clin. Oncol.* **2007**, *25* (2), 209–216. https://doi.org/10.1200/JCO.2006.09.0803.
(31) Jardim, D. L.; Groves, E. S.; Breitfeld, P. P.; Kurzrock, R. Factors Associated with Failure of Oncology Drugs in Late-Stage Clinical Development: A Systematic Review. *Cancer Treat. Rev.* **2017**, *52*, 12–21. https://doi.org/10.1016/j.ctrv.2016.10.009.
(32) Roberts, T. G.; Lynch, T. J.; Chabner, B. A. The Phase III Trial in the Era of Targeted Therapy: Unraveling the "Go or No Go" Decision. *J. Clin. Oncol.* **2003**, *21* (19), 3683–3695. https://doi.org/10.1200/JCO.2003.01.204.
(33) SALCHER-KONRAD, M.; NACI, H.; DAVIS, C. Approval of Cancer Drugs With Uncertain Therapeutic Value: A Comparison of Regulatory Decisions in Europe and the United States. *Milbank Q.* **2020**, *98* (4), 1219–1256. https://doi.org/10.1111/1468-0009.12476.
(34) Banzi, R.; Gerardi, C.; Bertele', V.; Garattini, S. Approvals of Drugs with Uncertain Benefit–Risk Profiles in Europe. *Eur. J. Intern. Med.* **2015**, *26* (8), 572–584. https://doi.org/10.1016/j.ejim.2015.08.008.
(35) Martinalbo, J.; Bowen, D.; Camarero, J.; Chapelin, M.; Démolis, P.; Foggi, P.; Jonsson, B.; Llinares, J.; Moreau, A.; O'Connor, D.; Oliveira, J.; Vamvakas, S.; Pignatti, F. Early Market Access of Cancer Drugs in the EU. *Ann. Oncol.* **2016**, *27* (1), 96–105. https://doi.org/10.1093/annonc/mdv506.
(36) Morris, Z. S.; Wooding, S.; Grant, J. The Answer Is 17 Years, What Is the Question: Understanding Time Lags in Translational Research. *J. R. Soc. Med.* **2011**, *104* (12), 510–520. https://doi.org/10.1258/jrsm.2011.110180.

(37) Medlinskiene, K.; Tomlinson, J.; Marques, I.; Richardson, S.; Stirling, K.; Petty, D. Barriers and Facilitators to the Uptake of New Medicines into Clinical Practice: A Systematic Review. *BMC Health Serv. Res.* **2021**, *21* (1), 1198. https://doi.org/10.1186/s12913-021-07196-4.
(38) Martin, E.; Pourtau, L.; Di Palma, M.; Delaloge, S. New Oral Targeted Therapies for Metastatic Breast Cancer Disrupt the Traditional Patients' Management—A Healthcare Providers' View. *Eur. J. Cancer Care (Engl.)* **2017**, *26* (6), e12624. https://doi.org/10.1111/ecc.12624.
(39) Rickwood, S.; Pereira, F.; Gómez, C. A. Attracting Investment in Clinical Development.
(40) Salmivalli, L. FinTrials – Kliinisten lääketutkimusten kansallinen toimintamalli.
(41) *Clinical Trials Regulation | European Medicines Agency (EMA)*. https://www.ema.europa.eu/en/human-regulatory-overview/research-development/clinical-trials-human-medicines/clinical-trials-regulation (accessed 2026-02-21).
(42) *Authorisation of medicines | European Medicines Agency (EMA)*. https://www.ema.europa.eu/en/about-us/what-we-do/authorisation-medicines (accessed 2026-01-20).
(43) Hwang, T. J.; Kesselheim, A. S.; Tibau, A.; Lee, C. C.; Vokinger, K. N. Clinical Benefit and Expedited Approval of Cancer Drugs in the United States, European Union, Switzerland, Japan, Canada, and Australia. *JCO Oncol. Pract.* **2022**, *18* (9), e1522–e1532. https://doi.org/10.1200/OP.21.00909.
(44) *Reform of the EU pharmaceutical legislation - Public Health*. https://health.ec.europa.eu/medicinal-products/legal-framework-governing-medicinal-products-human-use-eu/reform-eu-pharmaceutical-legislation_en (accessed 2026-02-03).
(45) Danzon, P. M.; Epstein, A. J. Effects of Regulation on Drug Launch and Pricing in Interdependent Markets. In *The Economics of Medical Technology*; Bolin, K., Kaestner, R., Eds.; Emerald Group Publishing Limited, 2012; Vol. 23, p 0. https://doi.org/10.1108/S0731-2199(2012)0000023005.
(46) Lanjouw, J. O. Patents, Price Controls and Access to New Drugs: How Policy Affects Global Market Entry. **2005**. https://doi.org/10.2139/ssrn.997353.
(47) Siddiqui, M.; Rajkumar, S. V. The High Cost of Cancer Drugs and What We Can Do About It. *Mayo Clin. Proc.* **2012**, *87* (10), 935–943. https://doi.org/10.1016/j.mayocp.2012.07.007.
(48) Vokinger, K. N.; Hwang, T. J.; Daniore, P.; Lee, C. C.; Tibau, A.; Grischott, T.; Rosemann, T. J.; Kesselheim, A. S. Analysis of Launch and Postapproval Cancer Drug Pricing, Clinical Benefit, and Policy Implications in the US and Europe. *JAMA Oncol.* **2021**, *7* (9), e212026. https://doi.org/10.1001/jamaoncol.2021.2026.
(49) Kleijnen, S.; Lipska, I.; Leonardo Alves, T.; Meijboom, K.; Elsada, A.; Vervölgyi, V.; d'Andon, A.; Timoney, A.; Leufkens, H. G.; De Boer, A.; Goettsch, W. G. Relative Effectiveness Assessments of Oncology Medicines for Pricing and Reimbursement Decisions in European Countries. *Ann. Oncol.* **2016**, *27* (9), 1768–1775. https://doi.org/10.1093/annonc/mdw233.
(50) Kleijnen, S.; George, E.; Goulden, S.; d'Andon, A.; Vitré, P.; Osińska, B.; Rdzany, R.; Thirstrup, S.; Corbacho, B.; Nagy, B. Z.; Leufkens, H. G.; de Boer, A.; Goettsch, W. G. Relative Effectiveness Assessment of Pharmaceuticals: Similarities and Differences in 29 Jurisdictions. *Value Health* **2012**, *15* (6), 954–960. https://doi.org/10.1016/j.jval.2012.04.010.
(51) OECD; European Commission. *EU Country Cancer Profile: Finland 2025*; EU Country Cancer Profiles; OECD Publishing, 2025. https://doi.org/10.1787/1b14100d-en.
(52) Hofmarcher, T.; Manzano, A.; Svedman, C.; Wilking, N. 2285MO Disparities in Uptake of New Cancer Medicines across 27 European Countries and Their Economic Drivers. *Ann. Oncol.* **2025**, *36*, S1173–S1174. https://doi.org/10.1016/j.annonc.2025.08.2901.
(53) Chaudoir, S. R.; Dugan, A. G.; Barr, C. H. Measuring Factors Affecting Implementation of Health Innovations: A Systematic Review of Structural, Organizational, Provider, Patient, and Innovation Level Measures. *Implement. Sci.* **2013**, *8* (1), 22. https://doi.org/10.1186/1748-5908-8-22.
(54) Wenzl, M.; Chapman, S. Performance-Based Managed Entry Agreements for New Medicines in OECD Countries and EU Member States: How They Work and Possible Improvements Going Forward. *OECD Health Work. Pap.* **2019**. https://doi.org/10.1787/6e5e4c0f-en.
(55) Efthymiadou, O.; Kanavos, P. Impact of Managed Entry Agreements on Availability of and Timely Access to Medicines: An Ex-Post Evaluation of Agreements Implemented for Oncology Therapies in Four Countries. *BMC Health Serv. Res.* **2022**, *22* (1), 1066. https://doi.org/10.1186/s12913-022-08437-w.

(56) *Nordic health care systems: recent reforms and current policy challenges*. OBS. https://eurohealthobservatory.who.int/publications/m/nordic-health-care-systems-recent-reforms-and-current-policy-challenges (accessed 2026-02-05).
(57) *Health technology assessment - Global*. https://www.who.int/health-topics/health-technology-assessment (accessed 2026-02-12).
(58) O'Donnell, J. C.; Pham, S. V.; Pashos, C. L.; Miller, D. W.; Smith, M. D. Health Technology Assessment: Lessons Learned from Around the World—An Overview. *Value Health* **2009**, *12*, S1–S5. https://doi.org/10.1111/j.1524-4733.2009.00550.x.
(59) Schoot, R. A.; Otth, M. A.; Frederix, G. W. J.; Leufkens, H. G. M.; Vassal, G. Market Access to New Anticancer Medicines for Children and Adolescents with Cancer in Europe. *Eur. J. Cancer* **2022**, *165*, 146–153. https://doi.org/10.1016/j.ejca.2022.01.034.
(60) Crean, B.; Parry, D.; Horsfield, A.; Ryan, J.; Oraiopoulos, N. HTA304 The Impact of Different HTA Frameworks on Time to Patient Access: A Case Study Assessing the First Commercial Launch Indications for Lynparza, Tagrisso, Imfinzi, Calquence and Enhertu. *Value Health* **2023**, *26* (12), S379. https://doi.org/10.1016/j.jval.2023.09.1987.
(61) Fontrier, A.-M.; Visintin, E.; Kanavos, P. Similarities and Differences in Health Technology Assessment Systems and Implications for Coverage Decisions: Evidence from 32 Countries. *PharmacoEconomics Open* **2021**, *6* (3), 315–328. https://doi.org/10.1007/s41669-021-00311-5.
(62) Vreman, R. A.; Mantel-Teeuwisse, A. K.; Hövels, A. M.; Leufkens, H. G. M.; Goettsch, W. G. Differences in Health Technology Assessment Recommendations Among European Jurisdictions: The Role of Practice Variations. *Value Health* **2020**, *23* (1), 10–16. https://doi.org/10.1016/j.jval.2019.07.017.
(63) *Drug launch in the Nordics*. https://www.abacusmedicinepharmaceuticals.com/drug-launch-nordics/ (accessed 2026-02-09).
(64) *Cancer care migrates to outpatient setting – The Journal of Healthcare Contracting*. https://www.jhconline.com/cancer-care-migrates-to-outpatient-setting-2.html (accessed 2026-01-22).
(65) Hansen, D. K.; Liu, Y.-H.; Ranjan, S.; Bhandari, H.; Potluri, R.; McFarland, L.; De Braganca, K. C.; Huo, S. The Impact of Outpatient versus Inpatient Administration of CAR-T Therapies on Clinical, Economic, and Humanistic Outcomes in Patients with Hematological Cancer: A Systematic Literature Review. *Cancers* **2023**, *15* (24), 5746. https://doi.org/10.3390/cancers15245746.
(66) Lääkkeiden arviointiprosessien ja -kriteereiden lähentäminen : Työryhmän raportti.
(67) Sosiaali- ja terveysministeriö. *Lääkkeiden hallinto ja valvonta*. Sosiaali- ja terveysministeriö. https://stm.fi/laakkeet/saadokset-ohjaus-ja-valvonta-yhteistyo (accessed 2025-08-06).
(68) *Laki Lääkealan turvallisuus- ja kehittämiskeskuksesta | 593/2009 | Lainsäädäntö | Finlex*. https://www.finlex.fi/fi/lainsaadanto/2009/593 (accessed 2026-02-10).
(69) *Lääkehoitojen arviointi (HTA)*. Fimea. https://fimea.fi/kehittaminen_ja_hta/laakehoitojen_arviointi (accessed 2026-02-10).
(70) *Terveydenhuoltolaki | 1326/2010 | Lainsäädäntö | Finlex*. https://www.finlex.fi/fi/lainsaadanto/2010/1326 (accessed 2026-02-10).
(71) *Suositusten käsittelyprosessi*. Palveluvalikoimaneuvosto. https://palveluvalikoima.fi/suositusten-kasittelyprosessi (accessed 2026-02-10).
(72) *Sairausvakuutuslaki | 1224/2004 | Lainsäädäntö | Finlex*. https://www.finlex.fi/fi/lainsaadanto/2004/1224 (accessed 2026-02-11).
(73) *Myyntiluvallinen lääkevalmiste - Uusi lääkevalmiste*. Lääkkeiden hintalautakunta. https://www.hila.fi/hakeminen-ja-ilmoitukset/korvattavuuden-ja-tukkuhinnan-hakeminen-ohjeet-uusi/myyntiluvalliset-uusi-laakevalmiste/ (accessed 2026-02-11).
(74) Laugesen, K.; Ludvigsson, J. F.; Schmidt, M.; Gissler, M.; Valdimarsdottir, U. A.; Lunde, A.; Sørensen, H. T. Nordic Health Registry-Based Research: A Review of Health Care Systems and Key Registries. *Clin. Epidemiol.* **2021**, *13*, 533–554. https://doi.org/10.2147/CLEP.S314959.
(75) *About SBU*. https://www.sbu.se/en/about-sbu/ (accessed 2026-02-27).
(76) *National Joint Introduction*. https://samverkanlakemedel.se/process---ordnat-inforande/national-joint-introduction (accessed 2026-02-26).
(77) *Information in English*. https://www.nyemetoder.no/en/english/ (accessed 2026-02-26).

(78) *Health technology assessments*. https://www.dmp.no/en/public-funding-and-pricing/health-technology-assessments (accessed 2026-02-26).
(79) *What are substitutable medicines?* https://www.dmp.no/en/public-funding-and-pricing/medicine-substitution-in-pharmacies/what-are-substitutable-medicines (accessed 2026-02-26).
(80) *In English*. https://medicinraadet.dk/om-os/in-english (accessed 2026-02-27).
(81) *New pharmaceuticals and negotiations - Amgros*. https://amgros.dk/en/pharmaceuticals/price-negotiations-and-tendering/new-pharmaceuticals-and-negotiations/ (accessed 2026-02-27).
(82) *Decisions*. Danish Medicines Agency. https://laegemiddelstyrelsen.dk/en/reimbursement/general-reimbursement/decisions/ (accessed 2026-02-27).
(83) Sathian, B.; Asim, M.; Banerjee, I.; Pizarro, A. B.; Roy, B.; van Teijlingen, E. R.; do Nascimento, I. J. B.; Alhamad, H. K. Impact of COVID-19 on Clinical Trials and Clinical Research: A Systematic Review. *Nepal J. Epidemiol.* **2020**, *10* (3), 878–887. https://doi.org/10.3126/nje.v10i3.31622.
(84) Kansallinen syöpästrategia 2026–2035.

Appendices

Appendix 1. Links to the publicly available data sources used in the study.

Data type	**Link to the data source**
Clinical trial activity (before EU CTR)	https://www.clinicaltrialsregister.eu/ctr-search/search
Clinical trial activity (after EU CTR)	https://euclinicaltrials.eu/search-for-clinical-trials/?lang=en
Regulatory approvals	https://www.ema.europa.eu/en/medicines
Market entry (Finland)	https://fimea.fi/en/databases_and_registers/fimeaweb
Market entry (Norway)	https://www.legemiddelsok.no
Market entry (Iceland)	https://www.lyfjastofnun.is/verd-og-greidsluthatttaka/lyfjaverdskra/
Market entry (Denmark)	https://laegemiddelstyrelsen.dk/en/sideeffects/find-medicines/lists-with-information-about-medicines/
Reimbursement (Sweden)	https://www.tlv.se/beslut/sok-priser-och-beslut-i-databasen.html
Recommendation (Sweden)	https://samverkanlakemedel.se/lakemedel---ordnat-inforande/arkiverade-rekommendationer

Appendix 2. EMA approved cancer medicines included in the study.

INN	Trade name	ATC code	MA date	MA type	Orphan status
Lenvatinib	Lenvima	L01EX08	28.5.2015	Standard	No
Nivolumab	Opdivo	L01FF01	19.6.2015	Standard	No
Pembrolizumab	Keytruda	L01FF02	17.7.2015	Standard	No
Panobinostat	Farydak	L01XH03	28.8.2015	Standard	No
Carfilzomib	Kyprolis	L01XG02	19.11.2015	Standard	No
Blinatumomab	Blincyto	L01FX07	23.11.2015	Standard	Yes
Venetoclax	Venclyxto	L01XX52	4.12.2016	Standard	No
Osimertinib	Tagrisso	L01EB04	1.2.2016	Standard	No
Cabozantinib	Cabometyx	L01EX07	9.9.2016	Standard	No
Palbociclib	Ibrance	L01EF01	9.11.2016	Standard	No
Daratumumab	Darzalex	L01FC01	20.5.2016	Standard	Yes
Ixazomib	Ninlaro	L01XG03	21.11.2016	Standard	Yes
Trifluridine/Tipiracil	Lonsurf	L01BC59	25.4.2016	Standard	No
Atezolizumab	Tecentriq	L01FF05	20.9.2017	Standard	No
Niraparib	Zejula	L01XK02	16.11.2017	Standard	Yes
Ribociclib	Kisqali	L01EF02	22.8.2017	Standard	No
Avelumab	Bavencio	L01FF04	18.9.2017	Standard	No
Tivozanib	Fotivda	L01EK03	24.8.2017	Standard	No
Midostaurin	Rydapt	L01EX10	18.9.2017	Standard	Yes
Alectinib	Alecensa	L01ED03	16.2.2017	Standard	No
Lutetium (177Lu) oxodotreotide	Lutathera	V10XX04	26.9.2017	Standard	Yes
Tisagenlecleucel	Kymriah	L01XL04	23.8.2018	Standard	Yes
Brigatinib	Alunbrig	L01ED04	22.11.2018	Standard	No
Durvalumab	Imfinzi	L01FF03	21.9.2018	Standard	No
Abemaciclib	Verzenios	L01EF03	26.9.2018	Standard	No
Encorafenib	Braftovi	L01EC03	19.9.2018	Standard	No
Binimetinib	Mektovi	L01EE03	20.9.2018	Standard	No
Rucaparib	Rubraca	L01XK03	23.5.2018	Standard	No
Axicabtagene Ciloleucel	Yescarta	L01XL03	23.8.2018	Standard	Yes
Talazoparib	Talzenna	L01XK04	20.6.2019	Standard	No
Apalutamide	Erleada	L02BB05	14.1.2019	Standard	No
Gilteritinib	Xospata	L01EX13	24.10.2019	Standard	Yes
Lorlatinib	Lorviqua	L01ED05	6.5.2019	Standard	No
Dacomitinib	Vizimpro	L01EB07	2.4.2019	Standard	No
Darolutamide	Nubeqa	L02BB06	27.3.2020	Standard	No
Acalabrutinib	Calquence	L01EL02	5.11.2020	Standard	No
Alpelisib	Piqray	L01EM03	27.7.2020	Standard	No
Isatuximab	Sarclisa	L01FC02	30.5.2020	Standard	No
Glasdegib	Daurismo	L01XJ03	26.6.2020	Standard	Yes
Avapritinib	Ayvakyt	L01EX18	24.9.2020	Conditional	Yes
Polatuzumab vedotin	Polivy	L01FX14	16.1.2020	Standard	Yes

Entrectinib	Rozlytrek	L01EX14	31.7.2020	Conditional	No
Duvelisib	Copiktra	L01EM04	19.5.2021	Standard	No
Tafasitamab	Minjuvi	L01FX12	26.8.2021	Conditional	Yes
Dostarlimab	Jemperli	L01FF07	21.4.2021	Standard	No
Ripretinib	Qinlock	L01EX19	18.11.2021	Standard	Yes
Pemigatinib	Pemazyre	L01EN02	26.3.2021	Conditional	Yes
Zanubrutinib	Brukinsa	L01EL03	22.11.2021	Standard	No
Selinexor	Nexpovio	L01XX66	26.3.2021	Standard	No
Idecaptagene vicleucel	Abecma	L01XL07	18.8.2021	Standard	Yes
Trastuzumab deruxtecan	Enhertu	L01FD04	18.1.2021	Conditional	No
Tucatinib	Tukysa	L01EH03	11.2.2021	Standard	No
Sacituzumab govitecan	Trodelvy	L01FX17	22.11.2021	Standard	No
Amivantamab	Rybrevant	L01FX18	9.12.2021	Standard	No
Selpercatinib	Retsevmo	L01EX22	11.2.2021	Conditional	No
Relugolix	Orgovyx	L02BX04	29.4.2022	Standard	No
Relatlimab/ Nivolumab	Opdualag	L01FY02	15.9.2022	Standard	No
Sotorasib	Lumykras	L01XX73	6.1.2022	Conditional	No
Asciminib	Scemblix	L01EA06	25.8.2022	Standard	Yes
Ciltacabtagene Autoleucel	Carvykti	L01XL05	25.5.2022	Standard	Yes
Lisocaptagene maraleucel	Breyanzi	L01XL08	4.4.2022	Standard	No
Lutetium (177Lu) vipivotide tetraxetan	Pluvicto	V10XX05	9.12.2022	Standard	No
Enfortumab vedotin	Padcev	L01FX13	13.4.2022	Standard	No
Melphalan flufenamide	Pepaxti	L01AA10	17.8.2022	Standard	No
Teclistamab	Tecvayli	L01FX24	23.8.2022	Conditional	No
Tremelimumab	Imjudo	L01FX20	20.2.2023	Standard	No
Tislelizumab	Tevimbra	L01FF09	15.9.2023	Standard	No
Ivosidenib	Tibsovo	L01XM02	4.5.2023	Standard	Yes
Elranatamab	Elrexfio	L01FX32	7.12.2023	Conditional	No
Epcoritamab	Tepkinly	L01FX27	22.9.2023	Conditional	No
Pirtobrutinib	Jaypirca	L01EL05	30.10.2023	Conditional	No
Elacestrant	Orserdu	L02BA04	15.9.2023	Standard	No
Glofitamab	Columvi	L01FX28	7.7.2023	Standard	No
Capivasertib	Truqap	L01EX27	17.6.2024	Standard	No
Erdafitinib	Balversa	L01EN01	22.8.2024	Standard	No
Retifanlimab	Zynyz	L01FF10	19.4.2024	Standard	Yes
Adagrasib	Krazati	L01XX77	5.1.2024	Conditional	No
Belzutifan	Welireg	L01XX74	12.2.2025	Conditional	No
Tistotumab vedotin	Tivdak	L01FX23	28.3.2025	Standard	No
Zanidatamab	Ziihera	L01FD07	27.6.2025	Conditional	Yes
Lazertinib	Lazcluse	L01EB09	20.1.2025	Standard	No
Datopotamab deruxtecan	Datroway	L01FX35	4.4.2025	Standard	No
Inavolisib	Itovebi	L01EM06	18.7.2025	Standard	No

Appendix 3. Annual phase III (including phase II/III and III/IV) initiations of new cancer medicines across the Nordic countries.

Country	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**	**2024**
Finland	18	13	8	12	13	13	27	14	9	13
Sweden	25	18	23	26	14	16	26	19	12	23
Norway	6	6	10	9	16	11	26	19	6	17
Denmark	29	22	28	20	21	27	34	23	9	17
Iceland	0	0	0	0	0	0	1	1	0	0

Appendix 4. Drug-level clinical trial activity of EMA approved cancer medicines across the Nordic countries.

Drug	**Finland**	**Sweden**	**Norway**	**Denmark**	**Iceland**
Lenvatinib	3	2	2	4	0
Nivolumab	14	14	8	13	0
Pembrolizumab	18	29	21	38	0
Panobinostat	0	0	1	0	0
Carfilzomib	4	2	2	1	0
Blinatumomab	1	2	1	2	0
Venetoclax	6	9	5	9	0
Osimertinib	0	0	0	1	0
Cabozantinib	1	1	0	0	0
Palbociclib	2	1	2	2	0
Daratumumab	4	9	7	11	0
Ixazomib	0	2	0	2	0
Trifluridine/Tipiracil	0	2	0	0	0
Atezolizumab	10	6	5	16	0
Niraparib	3	2	3	3	0
Ribociclib	1	1	1	2	0
Avelumab	0	**3**	0	8	0
Tivozanib	0	0	0	1	0
Midostaurin	1	1	1	0	0
Alectinib	0	2	1	1	0
Lutetium (177Lu) oxodotreotide	0	1	0	0	0
Tisagenlecleucel	1	1	3	1	0
Brigatinib	1	2	1	1	0
Durvalumab	2	5	3	7	1
Abemaciclib	3	0	1	4	0
Encorafenib	2	1	4	2	0
Binimetinib	1	0	3	1	0
Rucaparib	1	0	0	2	0
Axicabtagene Ciloleucel	0	1	0	0	0
Talazoparib	1	1	2	0	0
Apalutamide	1	4	0	1	0
Gilteritinib	0	1	0	2	0
Lorlatinib	0	1	0	1	0
Dacomitinib	0	1	0	0	0
Darolutamide	3	4	0	0	0
Acalabrutinib	1	2	1	4	0
Alpelisib	3	2	1	2	0
Isatuximab	0	4	3	3	0
Glasdegib	0	1	0	0	0
Avapritinib	0	1	0	0	0
Polatuzumab vedotin	1	1	1	2	0
Entrectinib	0	1	0	0	0
Duvelisib	1	0	0	0	0

Tafasitamab	3	1	2	2	0
Dostarlimab	5	4	5	2	0
Ripretinib	1	1	2	0	0
Pemigatinib	1	1	1	1	0
Zanubrutinib	0	4	1	1	0
Selinexor	0	1	0	0	0
Idecaptagene vicleucel	0	1	0	0	0
Trastuzumab deruxtecan	1	4	1	5	0
Tucatinib	1	1	1	1	0
Sacituzumab govitecan	0	1	0	0	0
Amivantamab	0	1	0	1	0
Selpercatinib	0	0	1	1	0
Relugolix	1	2	1	1	0
Relatlimab/ Nivolumab	2	2	3	1	0
Sotorasib	0	2	0	2	0
Asciminib	0	1	2	3	0
Ciltacabtagene Autoleucel	1	2	1	2	0
Lisocaptagene maraleucel	0	1	0	0	0
Lutetium (177Lu) vipivotide tetraxetan	0	3	0	2	0
Enfortumab vedotin	0	1	0	1	0
Melphalan flufenamide	0	0	1	1	0
Teclistamab	0	1	2	3	0
Tremelimumab	1	1	0	2	0
Tislelizumab	1	0	0	0	0
Ivosidenib	1	2	1	1	0
Elranatamab	4	2	3	2	0
Epcoritamab	0	2	1	3	0
Pirtobrutinib	0	0	1	2	0
Elacestrant	0	0	0	1	0
Glofitamab	0	0	0	2	0
Capivasertib	0	1	0	1	0
Erdafitinib	0	0	0	2	0
Retifanlimab	0	1	1	1	0
Adagrasib	1	1	0	1	1
Belzutifan	4	3	2	2	0
Tistotumab vedotin	0	0	0	0	0
Zanidatamab	1	1	0	0	0
Lazertinib	0	1	0	1	0
Datopotamab deruxtecan	0	2	0	1	0
Inavolisib	0	0	0	1	0

Appendix 5. Access details of EMA approved cancer medicines in Finland.

Drug	**Date of market entry**	**Delay (days)**	**Date of first sales**	**Delay (days)**
Lenvatinib	15.6.2015	18	30.6.2015	33
Nivolumab	15.7.2015	26	31.7.2015	42
Pembrolizumab	10.3.2017	602	31.3.2017	623
Panobinostat	-	-	-	-
Carfilzomib	1.12.2015	12	30.11.2015	11
Blinatumomab	8.12.2015	15	31.12.2015	38
Venetoclax	1.10.2018	666	31.10.2018	696
Osimertinib	1.9.2016	213	31.3.2016	59
Cabozantinib	15.2.2017	159	31.8.2014	0
Palbociclib	15.11.2020	1467	30.11.2020	1482
Daratumumab	1.7.2016	42	31.7.2016	72
Ixazomib	1.3.2017	100	28.2.2017	99
Trifluridine/Tipiracil	9.10.2017	532	31.10.2017	554
Atezolizumab	2.10.2017	12	31.10.2017	41
Niraparib	1.7.2024	2419	31.5.2018	196
Ribociclib	1.10.2018	405	31.10.2018	435
Avelumab	15.10.2017	27	31.10.2017	43
Tivozanib	-	-	-	-
Midostaurin	15.11.2017	58	30.11.2017	73
Alectinib	1.6.2017	105	31.3.2017	43
Lutetium (177Lu) oxodotreotide	5.12.2018	435	-	-
Tisagenlecleucel	29.10.2018	67	-	-
Brigatinib	15.12.2018	23	31.12.2018	39
Durvalumab	15.10.2018	24	31.10.2018	40
Abemaciclib	17.12.2018	82	31.12.2018	96
Encorafenib	15.5.2019	238	31.5.2019	254
Binimetinib	15.5.2019	237	31.5.2019	253
Rucaparib	15.7.2025	2610	-	-
Axicabtagene Ciloleucel	1.7.2020	678	-	-
Talazoparib	1.8.2022	1138	31.8.2022	1168
Apalutamide	15.1.2020	366	31.1.2020	382
Gilteritinib	30.12.2019	67	31.12.2019	68
Lorlatinib	15.11.2019	193	30.11.2019	208
Dacomitinib	-	-	-	-
Darolutamide	28.4.2020	32	30.4.2020	34
Acalabrutinib	1.7.2023	968	31.3.2022	511
Alpelisib	1.2.2021	189	28.2.2021	216
Isatuximab	15.9.2020	108	30.9.2020	123
Glasdegib	-	-	-	-
Avapritinib	-	-	-	-

Polatuzumab vedotin	8.6.2020	144	30.6.2020	166
Entrectinib	7.12.2020	129	31.12.2020	153
Duvelisib	-	-	-	-
Tafasitamab	15.9.2021	20	30.9.2021	35
Dostarlimab	24.9.2021	156	30.9.2021	162
Ripretinib	-	-	-	-
Pemigatinib	1.6.2021	67	30.6.2021	96
Zanubrutinib	15.11.2022	358	30.11.2022	373
Selinexor	-	-	-	-
Idecaptagene vicleucel	-	-	-	-
Trastuzumab deruxtecan	15.4.2021	87	30.4.2021	102
Tucatinib	1.4.2022	414	30.4.2021	78
Sacituzumab govitecan	15.2.2022	85	28.2.2022	98
Amivantamab	15.2.2022	68	28.2.2022	81
Selpercatinib	15.2.2022	369	28.2.2022	382
Relugolix	1.6.2023	398	30.6.2023	427
Relatlimab/ Nivolumab	1.7.2023	289	31.7.2023	319
Sotorasib	1.2.2022	26	28.3.2022	81
Asciminib	1.1.2023	129	31.1.2023	159
Ciltacabtagene Autoleucel	-	-	-	-
Lisocaptagene maraleucel	-	-	-	-
Lutetium (177Lu) vipivotide tetraxetan	-	-	-	-
Enfortumab vedotin	1.7.2022	79	31.7.2022	109
Melphalan flufenamide	-	-	-	-
Teclistamab	15.11.2022	84	30.11.2022	99
Tremelimumab	4.4.2023	43	-	-
Tislelizumab	18.8.2025	703	-	-
Ivosidenib	17.7.2023	74	31.7.2023	88
Elranatamab	1.9.2024	269	-	-
Epcoritamab	15.4.2024	206	-	-
Pirtobrutinib	1.1.2024	63	31.1.2024	93
Elacestrant	-	-	-	-
Glofitamab	2.1.2024	179	31.1.2024	208
Capivasertib	-	-	-	-
Erdafitinib	15.11.2024	85	30.11.2024	100
Retifanlimab	-	-	-	-
Adagrasib	-	-	-	-
Belzutifan	1.9.2025	201	30.9.2025	230
Tistotumab vedotin	-	-	-	-
Zanidatamab	-	-	-	-
Lazertinib	-	-	-	-

Datopotamab deruxtecan	-	-	-	-
Inavolisib	-	-	-	-

Appendix 6. Access details of EMA approved cancer medicines in Sweden.

Drug	**Date of reimbursement/recommendation**	**Delay (days)**	**Date of first sales**	**Delay (days)**
Lenvatinib	3.12.2015	189	31.5.2015	3
Nivolumab	4.9.2015	77	30.6.2015	11
Pembrolizumab	4.9.2015	49	31.3.2017	623
Panobinostat	16.12.2022	2667	31.8.2015	3
Carfilzomib	16.12.2015	27	30.11.2015	11
Blinatumomab	1.7.2021	2047	31.12.2015	38
Venetoclax	1.5.2018	513	30.11.2017	361
Osimertinib	1.10.2017	608	31.3.2016	59
Cabozantinib	1.4.2018	569	31.8.2014	0
Palbociclib	1.7.2017	234	30.11.2016	21
Daratumumab	17.10.2016	150	30.6.2016	41
Ixazomib	1.6.2018	557	31.5.2018	556
Trifluridine/Tipiracil	24.9.2016	152	31.7.2016	97
Atezolizumab	8.8.2018	322	30.11.2017	71
Niraparib	1.12.2019	745	31.5.2018	196
Ribociclib	1.2.2018	163	31.10.2017	70
Avelumab	1.2.2018	136	30.11.2017	73
Tivozanib	28.9.2018	400	-	-
Midostaurin	31.1.2018	135	30.11.2017	73
Alectinib	25.11.2017	282	31.3.2017	43
Lutetium (177Lu) oxodotreotide	-	-	-	-
Tisagenlecleucel	8.3.2019	197	-	-
Brigatinib	14.12.2018	22	31.12.2018	39
Durvalumab	27.11.2018	67	30.9.2018	9
Abemaciclib	1.7.2019	278	31.12.2018	96
Encorafenib	1.4.2019	194	31.5.2019	254
Binimetinib	1.4.2019	193	31.5.2019	253
Rucaparib	1.2.2025	2446	31.1.2025	2445
Axicabtagene Ciloleucel	8.3.2019	197	-	-
Talazoparib	1.6.2021	712	31.8.2019	72
Apalutamide	1.5.2021	838	31.1.2020	382
Gilteritinib	1.3.2021	494	31.1.2020	99
Lorlatinib	27.9.2019	144	30.6.2019	55
Dacomitinib	14.6.2019	73	31.5.2019	59
Darolutamide	1.5.2021	400	31.5.2020	65
Acalabrutinib	1.6.2023	938	31.3.2021	146
Alpelisib	21.5.2021	298	31.10.2020	96
Isatuximab	-	-	31.7.2020	62
Glasdegib	-	-	-	-
Avapritinib	-	-	-	-

Polatuzumab vedotin	11.9.2022	969	30.6.2020	166
Entrectinib	21.5.2021	294	31.5.2021	304
Duvelisib	-	-	-	-
Tafasitamab	24.1.2022	151	31.10.2021	66
Dostarlimab	25.2.2022	310	31.8.2022	497
Ripretinib	-	-	-	-
Pemigatinib	20.9.2024	1274	31.5.2021	66
Zanubrutinib	1.6.2023	556	31.5.2023	555
Selinexor	28.4.2025	1494	30.9.2025	1649
Idecaptagene vicleucel	24.1.2022	159	-	-
Trastuzumab deruxtecan	18.2.2021	31	30.4.2021	102
Tucatinib	1.5.2022	444	28.2.2021	17
Sacituzumab govitecan	24.1.2022	63	28.2.2022	98
Amivantamab	14.3.2022	95	31.3.2022	112
Selpercatinib	27.1.2023	715	28.2.2022	382
Relugolix	20.10.2023	539	31.5.2023	397
Relatlimab/ Nivolumab	27.10.2022	42	31.7.2023	319
Sotorasib	26.8.2022	232	28.2.2022	53
Asciminib	9.11.2022	76	31.12.2022	128
Ciltacabtagene Autoleucel	1.7.2022	37	-	-
Lisocaptagene maraleucel	1.7.2022	88	-	-
Lutetium (177Lu) vipivotide tetraxetan	13.1.2023	35	-	-
Enfortumab vedotin	1.7.2022	79	31.7.2022	109
Melphalan flufenamide	-	-	-	-
Teclistamab	12.12.2022	111	30.11.2022	99
Tremelimumab	-	-	30.4.2023	69
Tislelizumab	27.6.2024	286	-	-
Ivosidenib	-	-	31.7.2023	88
Elranatamab	8.2.2024	63	29.2.2024	84
Epcoritamab	22.1.2024	122	31.10.2023	39
Pirtobrutinib	15.11.2024	382	30.11.2023	31
Elacestrant	-	-	-	-
Glofitamab	9.11.2023	125	31.8.2023	55
Capivasertib	-	-	30.10.2024	135
Erdafitinib	27.5.2025	278	31.12.2024	131
Retifanlimab	-	-	-	-
Adagrasib	-	-	-	-
Belzutifan	-	-	-	
Tistotumab vedotin	-	-	-	-
Zanidatamab	-	-	-	-
Lazertinib	-	-	-	-

Datopotamab deruxtecan	-	-	-	-
Inavolisib	-	-	30.11.2025	135

Appendix 7. Access details of EMA approved cancer medicines in Norway.

Drug	**Date of market entry**	**Delay (days)**
Lenvatinib	1.8.2015	65
Nivolumab	1.9.2015	74
Pembrolizumab	1.2.2017	565
Panobinostat	15.11.2015	79
Carfilzomib	1.2.2016	74
Blinatumomab	15.3.2016	113
Venetoclax	15.2.2017	73
Osimertinib	15.5.2016	104
Cabozantinib	15.12.2016	97
Palbociclib	15.12.2016	36
Daratumumab	1.9.2016	104
Ixazomib	1.3.2017	100
Trifluridine/Tipiracil	15.8.2017	477
Atezolizumab	1.1.2018	103
Niraparib	1.3.2020	836
Ribociclib	1.11.2017	71
Avelumab	15.11.2017	58
Tivozanib	1.2.2019	526
Midostaurin	1.2.2018	136
Alectinib	15.4.2017	58
Lutetium (177Lu) oxodotreotide	26.9.2017	0
Tisagenlecleucel	1.3.2019	190
Brigatinib	1.7.2019	221
Durvalumab	1.2.2019	133
Abemaciclib	15.1.2019	111
Encorafenib	1.7.2019	285
Binimetinib	1.7.2019	284
Rucaparib	15.10.2024	2337
Axicabtagene Ciloleucel	1.12.2022	1561
Talazoparib	15.11.2019	148
Apalutamide	15.1.2020	366
Gilteritinib	15.1.2020	83
Lorlatinib	1.7.2019	56
Dacomitinib	1.7.2019	90
Darolutamide	1.7.2020	96
Acalabrutinib	1.5.2021	177
Alpelisib	15.10.2020	80
Isatuximab	1.11.2020	155
Glasdegib	15.10.2020	111
Avapritinib	-	-

Polatuzumab vedotin	15.4.2020	90
Entrectinib	15.9.2020	46
Duvelisib	-	-
Tafasitamab	1.11.2021	67
Dostarlimab	15.8.2021	116
Ripretinib	-	-
Pemigatinib	15.5.2021	50
Zanubrutinib	15.12.2022	388
Selinexor	-	-
Idecaptagene vicleucel	-	-
Trastuzumab deruxtecan	15.5.2021	117
Tucatinib	1.11.2022	628
Sacituzumab govitecan	15.2.2022	85
Amivantamab	1.3.2022	82
Selpercatinib	15.12.2021	307
Relugolix	15.6.2024	778
Relatlimab/ Nivolumab	1.4.2023	198
Sotorasib	1.4.2022	85
Asciminib	1.3.2023	188
Ciltacabtagene Autoleucel	-	-
Lisocaptagene maraleucel	-	-
Lutetium (177Lu) vipivotide tetraxetan	-	-
Enfortumab vedotin	1.7.2022	79
Melphalan flufenamide	-	-
Teclistamab	1.11.2022	70
Tremelimumab	1.3.2025	740
Tislelizumab	1.8.2024	321
Ivosidenib	1.3.2024	302
Elranatamab	1.4.2024	116
Epcoritamab	1.2.2024	132
Pirtobrutinib	15.7.2024	259
Elacestrant	-	-
Glofitamab	1.3.2024	238
Capivasertib	1.3.2025	257
Erdafitinib	15.1.2025	146
Retifanlimab	-	-
Adagrasib	-	-
Belzutifan	-	-
Tistotumab vedotin	-	-
Zanidatamab	-	-
Lazertinib	-	-

Datopotamab deruxtecan	-	-
Inavolisib	-	-

Appendix 8. Access details of EMA approved cancer medicines in Denmark.

Drug	**Date of market entry**	**Delay (days)**
Lenvatinib	N/A	N/A
Nivolumab	N/A	N/A
Pembrolizumab	N/A	N/A
Panobinostat	N/A	N/A
Carfilzomib	N/A	N/A
Blinatumomab	N/A	N/A
Venetoclax	N/A	N/A
Osimertinib	N/A	N/A
Cabozantinib	N/A	N/A
Palbociclib	N/A	N/A
Daratumumab	N/A	N/A
Ixazomib	N/A	N/A
Trifluridine/Tipiracil	N/A	N/A
Atezolizumab	N/A	N/A
Niraparib	N/A	N/A
Ribociclib	N/A	N/A
Avelumab	N/A	N/A
Tivozanib	N/A	N/A
Midostaurin	N/A	N/A
Alectinib	N/A	N/A
Lutetium (177Lu) oxodotreotide	-	-
Tisagenlecleucel	N/A	N/A
Brigatinib	N/A	N/A
Durvalumab	N/A	N/A
Abemaciclib	N/A	N/A
Encorafenib	N/A	N/A
Binimetinib	N/A	N/A
Rucaparib	N/A	N/A
Axicabtagene Ciloleucel	N/A	N/A
Talazoparib	N/A	N/A
Apalutamide	N/A	N/A
Gilteritinib	N/A	N/A
Lorlatinib	N/A	N/A
Dacomitinib	-	-
Darolutamide	N/A	N/A
Acalabrutinib	N/A	N/A
Alpelisib	N/A	N/A
Isatuximab	N/A	N/A
Glasdegib	-	-
Avapritinib	N/A	N/A

Polatuzumab vedotin	N/A	N/A
Entrectinib	N/A	N/A
Duvelisib	-	-
Tafasitamab	N/A	N/A
Dostarlimab	N/A	N/A
Ripretinib	N/A	N/A
Pemigatinib	N/A	N/A
Zanubrutinib	N/A	N/A
Selinexor	-	-
Idecaptagene vicleucel	-	-
Trastuzumab deruxtecan	N/A	N/A
Tucatinib	N/A	N/A
Sacituzumab govitecan	N/A	N/A
Amivantamab	N/A	N/A
Selpercatinib	N/A	N/A
Relugolix	N/A	N/A
Relatlimab/ Nivolumab	N/A	N/A
Sotorasib	N/A	N/A
Asciminib	N/A	N/A
Ciltacabtagene Autoleucel	N/A	N/A
Lisocaptagene maraleucel	N/A	N/A
Lutetium (177Lu) vipivotide tetraxetan	-	-
Enfortumab vedotin	N/A	N/A
Melphalan flufenamide	-	-
Teclistamab	N/A	N/A
Tremelimumab	N/A	N/A
Tislelizumab	N/A	N/A
Ivosidenib	N/A	N/A
Elranatamab	N/A	N/A
Epcoritamab	N/A	N/A
Pirtobrutinib	-	-
Elacestrant	-	-
Glofitamab	N/A	N/A
Capivasertib	N/A	N/A
Erdafitinib	N/A	N/A
Retifanlimab	-	-
Adagrasib	-	-
Belzutifan	-	-
Tistotumab vedotin	-	-
Zanidatamab	-	-
Lazertinib	-	-

Datopotamab deruxtecan	-	-
Inavolisib	N/A	N/A

Appendix 9. Access details of EMA approved cancer medicines in Iceland.

Drug	**Date of market entry**	**Delay (days)**
Lenvatinib	1.12.2018	1283
Nivolumab	1.6.2016	348
Pembrolizumab	1.10.2015	76
Panobinostat	-	-
Carfilzomib	1.10.2016	317
Blinatumomab	1.4.2017	495
Venetoclax	1.12.2019	1092
Osimertinib	1.6.2019	1216
Cabozantinib	1.6.2018	630
Palbociclib	1.2.2017	84
Daratumumab	1.6.2017	377
Ixazomib	1.1.2019	771
Trifluridine/Tipiracil	1.9.2016	129
Atezolizumab	1.1.2018	103
Niraparib	1.10.2018	319
Ribociclib	1.11.2018	436
Avelumab	1.1.2022	1566
Tivozanib	-	-
Midostaurin	1.4.2018	195
Alectinib	1.6.2017	105
Lutetium (177Lu) oxodotreotide	1.3.2025	2713
Tisagenlecleucel	-	-
Brigatinib	1.2.2021	802
Durvalumab	1.6.2019	253
Abemaciclib	1.2.2023	1589
Encorafenib	1.8.2021	1047
Binimetinib	1.8.2021	1046
Rucaparib	-	-
Axicabtagene Ciloleucel	-	-
Talazoparib	1.9.2021	804
Apalutamide	1.2.2021	749
Gilteritinib	1.3.2022	859
Lorlatinib	1.4.2021	696
Dacomitinib	-	-
Darolutamide	1.1.2021	280
Acalabrutinib	1.1.2022	422
Alpelisib	1.5.2021	278
Isatuximab	-	-
Glasdegib	-	-
Avapritinib	-	-

Polatuzumab vedotin	15.3.2022	789
Entrectinib	1.5.2021	274
Duvelisib	-	-
Tafasitamab	-	-
Dostarlimab	-	-
Ripretinib	15.4.2023	513
Pemigatinib	15.12.2021	264
Zanubrutinib	1.12.2022	374
Selinexor	-	-
Idecaptagene vicleucel	-	-
Trastuzumab deruxtecan	1.10.2021	256
Tucatinib	1.12.2023	1023
Sacituzumab govitecan	1.4.2023	495
Amivantamab	1.2.2024	784
Selpercatinib	1.5.2022	444
Relugolix	1.10.2024	886
Relatlimab/ Nivolumab	-	-
Sotorasib	-	-
Asciminib	1.1.2024	494
Ciltacabtagene Autoleucel	-	-
Lisocaptagene maraleucel	-	-
Lutetium (177Lu) vipivotide tetraxetan	-	-
Enfortumab vedotin	1.2.2024	659
Melphalan flufenamide	-	-
Teclistamab	1.7.2023	312
Tremelimumab	-	-
Tislelizumab	-	-
Ivosidenib	15.5.2022	0
Elranatamab	1.8.2024	238
Epcoritamab	-	-
Pirtobrutinib	-	-
Elacestrant	-	-
Glofitamab	-	-
Capivasertib	-	-
Erdafitinib	1.6.2025	283
Retifanlimab	-	-
Adagrasib	-	-
Belzutifan	-	-
Tistotumab vedotin	-	-
Zanidatamab	-	-
Lazertinib	-	-

Datopotamab deruxtecan	-	-
Inavolisib	-	-